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The Iowa Administrative Code Supplement is published biweekly pursuant to Iowa Code section 17A.6. The Supplement contains replacement chapters to be inserted in the loose-leaf Iowa Administrative Code (IAC) according to instructions included with each Supplement. The replacement chapters incorporate rule changes which have been adopted by the agencies and filed with the Administrative Rules Coordinator as provided in Iowa Code sections 7.17 and 17A.4 to 17A.6. To determine the specific changes in the rules, refer to the Iowa Administrative Bulletin bearing the same publication date.

In addition to the changes adopted by agencies, the replacement chapters may reflect objection to a rule or a portion of a rule filed by the Administrative Rules Review Committee (ARRC), the Governor, or the Attorney General pursuant to Iowa Code section 17A.4(6); an effective date delay imposed by the ARRC pursuant to section 17A.4(7) or 17A.8(9); rescission of a rule by the Governor pursuant to section 17A.4(8); or nullification of a rule by the General Assembly pursuant to Article III, section 40, of the Constitution of the State of Iowa.

The Supplement may also contain replacement pages for the IAC Index or the Uniform Rules on Agency Procedure.

INSTRUCTIONS

FOR UPDATING THE

IOWA ADMINISTRATIVE CODE

Agency names and numbers in bold below correspond to the divider tabs in the IAC binders. New and replacement chapters included in this Supplement are listed below. Carefully remove and insert chapters accordingly.

Editor's telephone (515)281-3355 or (515)242-6873

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Remove Reserved Chapters 15 and 16 and Chapter 17
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CHAPTER 5
EXCEPTIONS

193B—5.1(544A) Definitions. The following definitions apply as used in Iowa Code chapter 544A and this chapter of the architectural examining board rules.

"Accessory buildings" means a building or structure of an accessory character and miscellaneous structures not classified in any specific occupancy or use. "Accessory buildings" shall be constructed, equipped and maintained to conform to the requirements corresponding to the fire and life hazard incidental to the buildings' occupancy. "Accessory buildings" is intended to encompass the uses listed in Group U of the 2015 International Building Code®.

"Agricultural building" means a structure designed to house farm implements, hay, grain, poultry, livestock or other agricultural products. For the purpose of this definition, this structure shall not contain habitable space or a place of employment where agricultural products are processed or treated or packaged; nor shall it be a place used by the public.

"Alter" or *"alteration"* means any change, addition or modification to an existing building in its construction or occupancy.

"Church" means a building or portion thereof intended for the performance of religious services.

"Commercial" or *"commercial use"* means the following:

1. The use of a building or structure, or a portion thereof, for office, professional, or service-type transactions, including storage of records and accounts.
2. The use of a building or structure, or a portion thereof, for the display and sale of merchandise, and involves stocks of goods, including wares or merchandise incidental to such purposes and accessible to the public.

"Commercial use" is intended to encompass the uses listed in Group B and Group M of the 2015 International Building Code®.

"Detached" means a structure separated by distance and not connected to another structure.

"Dwelling unit" means a single unit providing complete, independent living facilities for one or more persons, including permanent provisions for living, sleeping, eating, cooking and sanitation.

"Educational use" means the use of a building or structure, or a portion thereof used (1) by six or more persons at any one time for education purposes through twelfth grade; or (2) by six or more children for day care purposes. Rooms and spaces within places of religious worship providing such day care during religious functions and day cares serving five or fewer children shall be classified as part of the primary occupancy. "Educational use" is intended to encompass the uses listed in Group E of the 2015 International Building Code®.

"Factory-built buildings" means any structure which is, wholly or in substantial part, made, fabricated, formed, or assembled in manufacturing facilities for installation, or assembly and installation, on a building site. "Factory-built buildings" includes the terms "mobile home," "manufactured home," and "modular home."

"Family dwelling unit" means the same as "dwelling unit."

"Gross floor area" means the area included within the surrounding exterior walls of a building. Areas of the building not provided with surrounding walls shall be included in the building area if such areas are included within the horizontal projection of the supporting structure of the roof or floor above.

"Habitable space (room)" means a space in a structure for living, sleeping, eating or cooking. Bathrooms, toilet compartments, closets, halls, storage or utility space, and similar areas are not considered "habitable space."

"Hazardous use" means the use of a building or structure, or a portion thereof, which involves the manufacturing, processing, generation or storage of materials that constitute a physical or health hazard. "Hazardous use" is intended to encompass the uses listed in Group H of the 2015 International Building Code®.

"Industrial use" means the use of a building or structure, or a portion thereof, for assembling, disassembling, fabricating, finishing, manufacturing, packaging, repair, or processing operations that

are not classified as hazardous use. "Industrial use" is intended to encompass the uses listed in Group F of the 2015 International Building Code®.

"Institutional use" means the use of a building or structure, or a portion thereof, in which persons are receiving custodial or medical care, in which persons are detained for penal or correctional purposes or in which the liberty of the occupants is restricted. Day care facilities as defined in educational use are not considered institutional uses. "Institutional use" is intended to encompass the uses listed in Group I of the 2015 International Building Code®. Facilities with five or fewer persons receiving custodial care may be considered a residential use or be considered part of the primary occupancy as listed in Group I of the 2015 International Building Code®.

"International Building Code" is a model building code developed by the International Code Council. The 2015 International Building Code® is available from the state library of Iowa or the board or online at codes.iccsafe.org.

"Light industrial" means buildings not more than one story in height and not exceeding 10,000 square feet in gross floor area that involve fabrication or manufacturing of noncombustible materials which, during finishing, packing, or processing, are not classified as hazardous use.

"Mixed building use" means a building containing more than one use classification.

"Nonstructural alterations" means modifications to an existing building which do not include any changes to structural members of a building, or do not modify means of egress, handicap accessible routes, fire resistivity or other life safety concerns.

"Occupancy" means a purpose for which a building, or part thereof, is used or intended to be used.

"Outbuildings" means the same as "accessory buildings."

"Place of assembly of people or public gathering" means the use of a building or structure, or a portion thereof, for the gathering of persons such as for civic, social, or religious functions; recreation, food or drink consumption; or awaiting transportation. "Place of assembly of people or public gathering" is intended to encompass the uses listed in Group A of the 2015 International Building Code®. Places of assembly with occupancy of fewer than 50 people shall be considered part of the primary occupancy.

"Residential use" means the use of a building or structure, or a portion thereof, for sleeping purposes when not classified as an institutional use. "Residential use" is intended to encompass the uses listed in Group R of the 2015 International Building Code®.

"Story" means that portion of a building included between the upper surface of any floor and the upper surface of the floor or roof next above.

"Structural members" consists of building elements which carry an imposed load of weight and forces in addition to their own weight including, but not limited to, loads imposed by forces of gravity, wind, and earthquake. Structural members include, but are not limited to, footings, foundations, columns, load-bearing walls, beams, girders, purlins, rafters, joists, trusses, lintels, and lateral bracing.

"Use" means the same as "occupancy."

"Warehouses" or *"warehouse use"* means the use of a building or structure, or portion thereof, for storage that is not classified as a hazardous use. "Warehouse use" is intended to encompass the uses listed in Group S of the 2015 International Building Code®.

[**ARC 3853C**, IAB 6/20/18, effective 7/25/18]

193B—5.2(544A) Exceptions. An architect licensed in this state is required to perform professional architectural services for all buildings except those listed below. Persons who are not licensed architects may perform planning and design services in connection with any of the following:

5.2(1) Detached residential buildings containing 12 or fewer family dwelling units of not more than three stories and outbuildings in connection with the buildings.

5.2(2) Buildings used primarily for agricultural purposes including grain elevators and feed mills.

5.2(3) Nonstructural alterations to existing buildings which do not change the use of a building:

a. From any other use to a place of assembly of people or public gathering.

b. From any other use to a place of residence not exempted by subrule 5.2(1).

c. From an industrial or warehouse use to a commercial or office use not exempted by subrule 5.2(4).

5.2(4) Warehouses and commercial buildings not more than one story in height, and not exceeding 10,000 square feet in gross floor area; commercial buildings not more than two stories in height and not exceeding 6,000 square feet in gross floor area; and light industrial buildings.

5.2(5) Factory-built buildings which are not more than two stories in height and not exceeding 20,000 square feet in gross floor area or which are certified by a professional engineer registered under Iowa Code chapter 542B.

5.2(6) Churches and accessory buildings, whether attached or separate, not more than two stories in height and not exceeding 2,000 square feet in gross floor area.

[**ARC 3335C**, IAB 9/27/17, effective 11/1/17]

193B—5.3(544A) Building use. The following criteria shall be used when applying the exceptions outlined in Iowa Code section 544A.18 and rule 193B—5.2(544A):

5.3(1) Building use takes priority over size. In all cases, the use of the building takes priority over the size. For example, a place of assembly is not a commercial use, and would not constitute an exception even if the building is not more than one story in height and does not exceed more than 10,000 square feet in gross floor area.

5.3(2) Mixed building use. In the case that a building contains more than one use, the most stringent use is applied to the entire building when applying the exceptions. For example, a two-story building containing a 6,000 square foot commercial space as well as 6,000 square feet of residential space on the second floor would be considered a 12,000 square foot, two-story commercial building for the purposes of the exception matrix.

5.3(3) Agricultural buildings. Activities inherent to housing farm implements, farm inputs, farm products, and livestock or other agricultural products, such as record keeping, sanitation, storage of farm inputs, or equipment preparation, repair, or modifications, shall not be construed as a use in and of itself for the purposes of applying the exceptions. For example, welding operations to repair an implement or grain-handling equipment would not trigger the consideration of an agricultural building or a portion of the building as an industrial use.

5.3(4) Churches and accessory buildings. When under the height and gross floor area noted in the exception and encompassing uses inherent to a church or an accessory building as defined, these buildings are exempted, even if the use within the building would normally not be exempted. For example, a church used as a place of assembly with occupancy of more than 50 people but still under the height and gross floor area noted would still be exempted even though the occupancy would place the building in the nonexempted category.

[**ARC 3853C**, IAB 6/20/18, effective 7/25/18]

193B—5.4(544A) Exceptions matrix. The following matrix is compiled to illustrate the exceptions outlined in Iowa Code section 544A.18 and rule 193B—5.2(544A). The laws and rules governing the Practice of Engineering are not illustrated herein.

BUILDINGS NEW CONSTRUCTION			
Building Use Type	**Description**	**Architect Required**	**Architect May Not Be Required**
Agricultural use	Including grain elevators and feed mills		X
Churches and accessory buildings whether attached or separate	One or two stories in height, up to a maximum of 2,000 square feet in gross floor area		X
	Any number of stories in height, greater than 2,000 square feet in gross floor area	X	
	More than two stories in height	X	
Commercial use	One story in height, up to a maximum of 10,000 square feet in gross floor area		X
	One story in height, greater than 10,000 square feet in gross floor area	X	

BUILDINGS NEW CONSTRUCTION			
Building Use Type	**Description**	**Architect Required**	**Architect May Not Be Required**
	Two stories in height, up to a maximum of 6,000 square feet in gross floor area		X
	Two stories in height, greater than 6,000 square feet of gross floor area	X	
	More than two stories in height	X	
Detached residential use	One, two or three stories in height, containing 12 or fewer family dwelling units		X
	More than 12 family dwelling units	X	
	More than three stories in height	X	
	Outbuildings in connection with detached residential buildings		X
Educational use		X	
Hazardous use		X	
Industrial use		X	
Institutional use		X	
Light industrial use			X
Places of assembly		X	
Warehouse use	One story in height, up to a maximum of 10,000 square feet in gross floor area		X
	One story in height, greater than 10,000 square feet in gross floor area	X	
	More than one story in height	X	
Factory-built buildings	Any height and size, if certified by a professional engineer licensed under Iowa Code chapter 542B		X
	One or two stories in height, up to a maximum of 20,000 square feet in gross floor area		X
	One or two stories in height, greater than 20,000 square feet in gross floor area	X	
	More than two stories in height	X	
	More than 20,000 square feet in gross floor area	X	

ALTERATIONS TO EXISTING BUILDINGS			
Alteration Type	**Description**	**Architect Required**	**Architect May Not Be Required**
Structural alterations to exempt buildings	Modifications which change the structural members, means of egress, handicap accessible path, fire resistivity or other life safety concerns		X
Structural alterations to nonexempt buildings	Modifications which change the structural members, means of egress, handicap accessible path, fire resistivity or other life safety concerns	X	
Nonstructural alteration	Which does not modify means of egress, handicap accessible path, fire resistivity or other life safety concerns		X

ALTERATIONS TO EXISTING BUILDINGS				
Alteration Type	**Description**		**Architect Required**	**Architect May Not Be Required**
	Which maintains the previous type of use			X
Nonstructural alteration which changes the use of the building from any other use to:	A place of assembly of people or public gathering		X	
	Educational use		X	
	Hazardous use		X	
	Residential use exempted	and is one, two or three stories in height and contains not more than 12 family dwelling units		X
	Residential use not exempted otherwise	and is more than three stories in height	X	
		and containing more than 12 family dwelling units	X	
Nonstructural alterations which change the use of the building from industrial or warehouse to:	Commercial or office use	and is one story in height and not greater than a maximum of 10,000 square feet in gross floor area		X
		and is one story in height and greater than 10,000 square feet in gross floor area	X	
		and is two stories in height and not greater than a maximum of 6,000 square feet in gross floor area		X
		and is two stories in height and greater than 6,000 square feet in gross floor area	X	
		and is more than two stories in height	X	
		and is greater than 10,000 square feet of gross floor area	X	
Nonstructural alterations to:	Agricultural use	Including grain elevators and feed mills		X
	Churches and accessory building uses	One or two stories in height, up to a maximum of 2,000 square feet in gross floor area		X
		Any number of stories in height, greater than 2,000 square feet in gross floor area	X	
		More than two stories in height	X	
	Commercial use	One story in height, up to a maximum of 10,000 square feet in gross floor area		X
		One story in height, greater than 10,000 square feet in gross floor area	X	
		Two stories in height, up to a maximum of 6,000 square feet in gross floor area		X
		Two stories in height, greater than 6,000 square feet in gross floor area	X	
		More than two stories in height	X	
	Detached residential buildings	One, two or three stories in height, containing 12 or fewer family dwelling units		X
		More than 12 family dwelling units	X	
		More than three stories in height	X	
		Outbuildings in connection with detached residential buildings		X
	Educational use		X	
	Hazardous use		X	
	Industrial use		X	
	Institutional use		X	
	Light industrial use			X
	Places of assembly		X	

ALTERATIONS TO EXISTING BUILDINGS				
Alteration Type	**Description**		**Architect Required**	**Architect May Not Be Required**
	Warehouse use	One story in height, up to a maximum of 10,000 square feet in gross floor area		X
		One story in height, greater than 10,000 square feet in gross floor area	X	
		More than one story in height	X	
	Factory-built buildings	Any height and size if entire building is certified by a professional engineer licensed under Iowa Code chapter 542B		X
		One or two stories in height, up to a maximum of 20,000 square feet of gross floor area		X
		One or two stories in height, greater than 20,000 square feet in gross floor area	X	
		More than two stories in height	X	
		More than 20,000 square feet in gross floor area	X	

[**ARC 3853C**, IAB 6/20/18, effective 7/25/18]

These rules are intended to implement Iowa Code section 544A.18.

[Filed 9/12/01, Notice 6/27/01—published 10/3/01, effective 11/7/01]
[Filed ARC 3335C (Notice ARC 3172C, IAB 7/5/17), IAB 9/27/17, effective 11/1/17]
[Filed ARC 3853C (Notice ARC 3661C, IAB 2/28/18), IAB 6/20/18, effective 7/25/18]

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[Prior to 8/10/88, see College Aid Commission[245]]

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CHAPTER 1
ORGANIZATION AND OPERATION

[Prior to 8/10/88, see College Aid Commission, 245—Ch 12]

283—1.1(261) Purpose. This chapter describes the organization, operation, and location of the Iowa college student aid commission (hereinafter generally referred to as the commission, or the ICSAC) and describes the means by which any interested person may obtain information and make submittals or requests.

283—1.2(261) Organization and operations.

1.2(1) *Location.* The commission is located at 430 East Grand Avenue, Third Floor, Des Moines, Iowa 50309-1920; telephone (515)725-3400; Internet site www.iowacollegeaid.gov. Office hours are 8 a.m. to 4:30 p.m., Monday to Friday. Offices are closed on Saturdays and Sundays and on official state holidays designated in accordance with state law.

1.2(2) *The commission.* The commission consists of 15 members and functions under the leadership of a chairperson elected by the membership. Nine members are appointed by the governor to serve four-year terms. Four of the governor's appointees represent the general public, one represents parents of Iowa postsecondary students, one represents practitioners licensed under Iowa Code chapter 272, one represents Iowa independent colleges and universities, one represents Iowa community colleges, and one represents Iowa postsecondary students. One member is appointed by the board of regents. The president of the senate, the minority leader of the senate, the speaker of the house of representatives, and the minority leader of the house of representatives each appoint one ex officio, nonvoting commission member. The director of the department of education serves as a continuous member of the commission and may appoint a designee to represent the department of education.

1.2(3) *Meetings.* The commission shall meet at regular intervals at least six times annually, but not more than eight times in person annually.

a. The chairperson of the commission presides at each meeting. Members of the public may be recognized at the discretion of the chairperson. All meetings are open to the public in accordance with the open meetings law, Iowa Code chapter 21.

b. The commission shall give advance public notice of the time and place of each commission meeting. The notice will include the specific date, time, and place of the meeting.

c. A quorum shall consist of two-thirds of the voting members of the commission. When a quorum is present, a position is carried by an affirmative vote of the majority of commission members eligible to vote.

d. A specific time is set aside at each meeting for the public to address the commission. As a general guideline, a limit of five minutes will be allocated for each of these presentations. If a large group seeks to address a specific issue, the chairperson may limit the number of speakers. Members of the public who wish to address the commission during this portion of the meeting are required to notify the commission's administrative secretary prior to the meeting. The person's name and the subject of the person's remarks must be provided. To accommodate maximum public participation, members of the public are encouraged to submit requests at least 72 hours in advance of the meeting.

1.2(4) *Minutes.* The minutes of all commission meetings are recorded and kept by the executive director in the commission office. Upon approval by the commission, minutes are posted on the commission's Internet site.

1.2(5) *Records.* The records of all business transacted and other information with respect to the operation of the commission are public records and are on file in the commission office. All records, except statements specified as confidential under these rules, are available for inspection during regular business hours. Copies of records up to 25 pages in number may be obtained without charge. The cost of reproduction will be charged for pages in excess of 25. Digital media will be provided for a fee equal to the cost of the physical device provided. The charge may be waived by the executive director.

1.2(6) *Submission and requests.* Inquiries, submissions, petitions, and other requests directed to the commission may be made by letter addressed to the executive director at the address listed in subrule

1.2(1). Any person may petition for a written or oral hearing before the commission. All requests for a hearing must be in writing and state the specific subject to be discussed and the reasons a personal appearance is necessary if one is requested.

1.2(7) *Advisory councils.* Rescinded IAB 2/19/14, effective 3/26/14.

[**ARC 9391B**, IAB 2/23/11, effective 3/30/11; **ARC 1318C**, IAB 2/19/14, effective 3/26/14; **ARC 3699C**, IAB 3/28/18, effective 5/2/18; see Delay note at end of chapter; **ARC 3844C**, IAB 6/20/18, effective 5/18/18; **ARC 3854C**, IAB 6/20/18, effective 7/25/18]

These rules are intended to implement Iowa Code section 17A.3(1)*"a"* and *"b"* and chapter 261.

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[Filed ARC 1318C (Notice ARC 1123C, IAB 10/16/13), IAB 2/19/14, effective 3/26/14]
[Filed ARC 3699C (Notice ARC 3516C, IAB 12/20/17), IAB 3/28/18, effective 5/2/18][1]
[Filed Emergency ARC 3844C, IAB 6/20/18, effective 5/18/18]
[Filed ARC 3854C (Notice ARC 3711C, IAB 3/28/18), IAB 6/20/18, effective 7/25/18]

[1] May 2, 2018, effective date of 1.2(3) [ARC 3699C] delayed 70 days by the Administrative Rules Review Committee at its meeting held April 6, 2018.

CHAPTER 15
IOWA GUARANTEED LOAN PAYMENT PROGRAM
[Prior to 8/10/88, College Aid Commission, 245—Ch 14]
Rescinded **ARC 1870C**, IAB 2/18/15, effective 3/25/15

CHAPTER 16
WASHINGTON, D.C., INTERNSHIP GRANT
Rescinded **ARC 0396C**, IAB 10/17/12, effective 11/21/12

CHAPTER 17
BARBER AND COSMETOLOGY ARTS AND SCIENCES TUITION GRANT PROGRAM
Rescinded **ARC 3854C**, IAB 6/20/18, effective 7/25/18

CHAPTER 24
ACCREDITATION OF PROVIDERS OF SERVICES TO PERSONS WITH MENTAL ILLNESS, INTELLECTUAL DISABILITIES, OR DEVELOPMENTAL DISABILITIES

PREAMBLE

The mental health and disability services commission has adopted this set of standards to be met by all providers of services to people with mental illness, intellectual disabilities, or developmental disabilities. These standards apply to providers that are not required to be licensed by the department of inspections and appeals. These providers include community mental health centers, mental health services providers, case management providers, supported community living providers, and crisis response providers in accordance with Iowa Code chapter 225C.

The standards serve as the foundation of a performance-based review of those organizations for which the department holds accreditation responsibility, as set forth in Iowa Code chapters 225C and 230A. The mission of accreditation is to assure individuals using the services and the general public of organizational accountability for meeting best practices performance levels, for efficient and effective management, and for the provision of quality services that result in quality outcomes for individuals using the services.

The department's intent is to establish standards that are based on the principles of quality improvement and are designed to facilitate the provision of excellent quality services that lead to positive outcomes. The intent of these standards is to make organizations providing services responsible for effecting efficient and effective management and operational systems that enhance the involvement of individuals using the services and to establish a best practices level of performance by which to measure provider organizations.

[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

DIVISION I
SERVICES FOR INDIVIDUALS WITH DISABILITIES

PREAMBLE

This set of standards in this division has been established to be met by all providers of case management, day treatment, intensive psychiatric rehabilitation, supported community living, partial hospitalization, outpatient counseling and emergency services.

[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

441—24.1(225C) Definitions.

"Accreditation" means the decision made by the commission that the organization has met the applicable standards.

"Advanced registered nurse practitioner" means a nurse who has current licensure as a registered nurse in Iowa, or licensure in another state that is recognized in Iowa pursuant to Iowa Code chapter 152E, and who is also registered as certified in psychiatric mental health specialties pursuant to board of nursing rules in 655—Chapter 7.

"Advisory board" means the board that reviews and makes recommendations to the organization on the program being accredited. The advisory board shall meet at least three times a year and shall have at least three members, at least 51 percent of whom are not providers. The advisory board shall include representatives who have disabilities or family members of persons with disabilities. The advisory board's duties include review and recommendation of policies, development and review of the organizational plan for the program being accredited, review and recommendation of the budget for the program being accredited, and review and recommendation of the performance improvement program of the program being accredited.

"Anticipated discharge plan" means the statement of the condition or circumstances by which the individual using the service would no longer need each of the specific services accredited under this chapter.

"Appropriate" means the degree to which the services or supports or activities provided or undertaken by the organization are suitable and desirable for the needs, situation, or problems of the individual using the service.

"Assessment" means the review of the current functioning of the individual using the service in regard to the individual's situation, needs, strengths, abilities, desires and goals.

"Benchmarks" means the processes of an organization that lead to implementation of the indicators.

"Chronic mental illness" means the condition present in people aged 18 and over who have a persistent mental or emotional disorder that seriously impairs their functioning relative to such primary aspects of daily living as personal relations, living arrangements, or employment. People with chronic mental illness typically meet at least one of the following criteria:

1. They have undergone psychiatric treatment more intensive than outpatient care more than once in a lifetime (e.g., emergency services, alternative home care, partial hospitalization or inpatient hospitalization).
2. They have experienced at least one episode of continuous, structured, supportive residential care other than hospitalization.

In addition, people with chronic mental illness typically meet at least two of the following criteria on a continuing or intermittent basis for at least two years:

1. They are unemployed, employed in a sheltered setting, or have markedly limited skills and a poor work history.
2. They require financial assistance for out-of-hospital maintenance and may be unable to procure this assistance without help.
3. They show severe inability to establish or maintain a personal social support system.
4. They require help in basic living skills.
5. They exhibit inappropriate social behavior that results in demand for intervention by the mental health or judicial system.

In atypical instances, a person who varies from these criteria could still be considered to be a person with chronic mental illness.

"Commission" means the mental health and disability services commission (MH/DS commission) as established and defined in Iowa Code section 225C.5.

"Community" means a natural setting where people live, learn, work, and socialize.

"Community mental health center" means an organization providing mental health services that is established pursuant to Iowa Code chapters 225C and 230A.

"Crisis intervention plan" means a personalized, individualized plan developed with the individual using the service that identifies potential personal psychiatric, environmental, and medical emergencies. This plan shall also include those life situations identified as problematic and the identified strategies and natural supports developed with the individual using the service to enable the individual to self-manage, alleviate, or end the crisis. This plan shall also include how the individual can access emergency services that may be needed.

"Deemed status" means acceptance by the commission of accreditation or licensure of a program or service by another accrediting body in lieu of accreditation based on review and evaluation by the division.

"Department" means the Iowa department of human services.

"Developmental disability" means a severe, chronic disability that:

1. Is attributable to a mental or physical impairment or combination of mental and physical impairments;
2. Is manifested before the age of 22;
3. Is likely to continue indefinitely;
4. Results in substantial functional limitations in three or more of the following areas of major life activity: self-care, receptive and expressive language, learning, mobility, self-direction, capacity for independent living, and economic self-sufficiency; and

5. Reflects the person's need for a combination and sequence of special, interdisciplinary, or generic services, individualized supports, or other forms of assistance that are of lifelong or extended duration and are individually planned and coordinated.

A person from birth to the age of nine, inclusive, who has a substantial developmental delay or specific congenital or acquired condition may be considered to have a developmental disability without meeting three or more of the criteria described above if the person, without services and supports, has a high probability of meeting those criteria later in life.

"Direct services" means services providing therapy, habilitation, or rehabilitation activities or support services such as transportation.

"Division" means the division of behavioral, developmental, and protective services for families, adults, and children of the department of human services.

"Doctor of medicine or osteopathic medicine" means a person who is licensed in the state of Iowa under Iowa Code chapter 148 as a physician and surgeon or under Iowa Code chapter 150A as an osteopathic physician and surgeon.

"Functional assessment" means the analysis of daily living skills. The functional assessment also takes into consideration the strengths, stated needs, and level and kind of disability of the individual using the service.

"Goal achieving" means to gain the required skills and supports to obtain the goal of choice. For purposes of this chapter, the definition and explanation are taken from the Psychiatric Rehabilitation Practitioner Tools, as developed by the Boston Center for Psychiatric Rehabilitation.

"Goal keeping" means assisting the individual using the service in maintaining successful and satisfying role performance to prevent the emergence of symptoms associated with role deterioration. For purposes of this chapter, the definition and explanation are taken from the Psychiatric Rehabilitation Practitioner Tools, as developed by the Boston Center for Psychiatric Rehabilitation.

"Incident," for the purposes of this chapter, means an occurrence involving the individual using the service that:

1. Results in a physical injury to or by the individual that requires a physician's treatment or admission to a hospital, or
2. Results in someone's death, or
3. Requires emergency mental health treatment for the individual, or
4. Requires the intervention of law enforcement, or
5. Results from any prescription medication error, or
6. Is reportable to protective services.

"Indicators" means conditions that will exist when the activity is done competently and benchmarks are achieved. Indicators also provide a means to assess the activity's effect on outcomes of services.

"Informed consent" refers to time-limited, voluntary consent. The individual using the service or the individual's legal guardian may withdraw consent at any time without risk of punitive action. "Informed consent" includes a description of the treatment and specific procedures to be followed, the intended outcome or anticipated benefits, the rationale for use, the risks of use and nonuse, and the less restrictive alternatives considered. The individual using the service or the legal guardian has the opportunity to ask questions and have them satisfactorily answered.

"Intellectual disability" means a diagnosis of intellectual disability (intellectual developmental disorder), global developmental delay, or unspecified intellectual disability (intellectual developmental disorder) under these rules which shall be made only when the onset of the person's condition was during the developmental period and shall be based on an assessment of the person's intellectual functioning and level of adaptive skills. A licensed psychologist or psychiatrist who is professionally trained to administer the tests required to assess intellectual functioning and to evaluate a person's adaptive skills shall make the diagnosis. A diagnosis of intellectual disability shall be made in accordance with the criteria provided in the current version of the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association.

"Intensive psychiatric rehabilitation practitioner" means a person who has at least 60 contact hours of training in intensive psychiatric rehabilitation and either:

1. Is certified as a psychiatric rehabilitation practitioner by the United States Psychiatric Rehabilitation Association; or

2. Holds a bachelor's degree with 30 semester hours or equivalent quarter hours in a human services field (including, but not limited to, psychology, social work, mental health counseling, marriage and family therapy, nursing, education, occupational therapy, and recreational therapy) and has at least one year of experience in the delivery of services to the population groups that the person is hired to serve.

"Leadership" means the governing board, the chief administrative officer or executive director, managers, supervisors, and clinical leaders who participate in developing and implementing organizational policies, plans and systems.

"Marital and family therapist" means a person who is licensed under Iowa Code chapter 154D in the application of counseling techniques in the assessment and resolution of emotional conditions. This includes the alteration and establishment of attitudes and patterns of interaction relative to marriage, family life, and interpersonal relationships.

"Mental health counselor" means a person who is licensed under Iowa Code chapter 154D in counseling services involving assessment, referral, consultation, and the application of counseling, human development principles, learning theory, group dynamics, and the etiology of maladjustment and dysfunctional behavior to individuals, families, and groups.

"Mental health professional" means a person who meets all of the following conditions:

1. Holds at least a master's degree in a mental health field including, but not limited to, psychology, counseling and guidance, psychiatric nursing and social work; or is a doctor of medicine or osteopathic medicine; and

2. Holds a current Iowa license when required by the Iowa professional licensure laws (such as a psychiatrist, a psychologist, a marital and family therapist, a mental health counselor, an advanced registered nurse practitioner, a psychiatric nurse, or a social worker); and

3. Has at least two years of postdegree experience supervised by a mental health professional in assessing mental health problems, mental illness, and service needs and in providing mental health services.

"Mental health service provider" means an organization whose services are established to specifically address mental health services to individuals or the administration of facilities in which these services are provided. Organizations included are:

1. Those contracting with a county board of supervisors to provide mental health services in lieu of that county's affiliation with a community mental health center (Iowa Code chapter 230A).

2. Those that may contract with a county board of supervisors for special services to the general public or special segments of the general public and that are not accredited by any other accrediting body.

These standards do not apply to individual practitioners or partnerships of practitioners covered under Iowa's professional licensure laws.

"Natural supports" means those services and supports an individual using the service identifies as wanted or needed that are provided at no cost by family, friends, neighbors, and others in the community, or by organizations or entities that serve the general public.

"New organization" means an entity that has never been accredited under 441—Chapter 24 or an accredited entity under 441—Chapter 24 that makes a significant change in its ownership, structure, management, or service delivery.

"Organization" means:

1. A governmental entity or an entity that meets Iowa Code requirements for a business organization as a for-profit or not-for-profit business. These entities include, but are not limited to, a business corporation under Iowa Code chapter 490 or a nonprofit corporation under Iowa Code chapter 504 that provides a service accredited pursuant to the rules in this chapter.

2. A county, consortium of counties, or the department of human services that provides or subcontracts for the provision of case management.

3. A division or unit of a larger entity, such as a unit within a hospital or parent organization.

"Organization" does not include: an individual for whom a license to engage in a profession is required under Iowa Code section 147.2, any person providing a service if the person is not organized as a corporation or other business entity recognized under the Iowa Code, or an entity that provides only financial, administrative, or employment services and that does not directly provide the services accredited under this chapter.

"Outcome" means the result of the performance or nonperformance of a function or process or activity.

"Policies" means the principles and statements of intent of the organization.

"Procedures" means the steps taken to implement the policies of the organization.

"Program" means a set of related resources and services directed to the accomplishment of a fixed set of goals for the population of a specified geographic area or for special target populations.

"Psychiatric crisis intervention plan" means a personalized, individualized plan developed with the individual using the service that identifies potential personal psychiatric emergencies. This plan shall also include those life situations identified as problematic and the identified strategies and natural supports developed with the individual using the service to enable the individual to self-manage, alleviate, or end the crisis. This plan shall also include how the individual can access emergency services that may be needed.

"Psychiatric nurse" means a person who meets the requirements of a certified psychiatric nurse, is eligible for certification by the American Nursing Association, and is licensed by the state of Iowa to practice nursing as defined in Iowa Code chapter 152.

"Psychiatrist" means a doctor of medicine or osteopathic medicine who is certified by the American Board of Psychiatry and Neurology or who is eligible for certification and who is fully licensed to practice medicine in the state of Iowa.

"Psychologist" means a person who:

1. Is licensed to practice psychology in the state of Iowa or meets the requirements of eligibility for a license to practice psychology in the state of Iowa as defined in Iowa Code chapter 154B; or
2. Is certified by the Iowa department of education as a school psychologist or is eligible for certification by the Iowa department of education.

"Qualified case managers and supervisors" means people who have the following qualifications:

1. A bachelor's degree with 30 semester hours or equivalent quarter hours in a human services field (including, but not limited to, psychology, social work, mental health counseling, marriage and family therapy, nursing, education, occupational therapy, and recreational therapy) and at least one year of experience in the delivery of services to the population groups that the person is hired as a case manager or case management supervisor to serve; or
2. An Iowa license to practice as a registered nurse and at least three years of experience in the delivery of services to the population group the person is hired as a case manager or case management supervisor to serve.

People employed as case management supervisors on or before August 1, 1993, who do not meet these requirements shall be considered to meet these requirements as long as they are continuously employed by the same case management provider.

"Readiness assessment" means a process of involving the individual using the service in clarifying motivational readiness to participate in the recovery process. For purposes of this chapter, the definition and explanation are taken from the Psychiatric Rehabilitation Practitioner Tools, as developed by the Boston Center for Psychiatric Rehabilitation.

"Readiness development" means services designed to develop or increase an individual's interest, motivation, and resolve to engage in the rehabilitation services process, as a means of enhancing independent functioning and quality of life. For purposes of this chapter, the definition and explanation are taken from the Psychiatric Rehabilitation Practitioner Tools, as developed by the Boston Center for Psychiatric Rehabilitation.

"Registered nurse" means a person who is licensed to practice nursing in the state of Iowa as defined in Iowa Code chapter 152.

"Rehabilitation services" means services designed to restore, improve, or maximize the individual's optimal level of functioning, self-care, self-responsibility, independence and quality of life and to minimize impairments, disabilities and dysfunction caused by a serious and persistent mental or emotional disability.

"Rights restriction" means limitations not imposed on the general public in the areas of communication, mobility, finances, medical or mental health treatment, intimacy, privacy, type of work, religion, place of residence, and people with whom the individual using the service may share a residence.

"Serious emotional disturbance" means a diagnosable mental, behavioral, or emotional disorder that (1) is of sufficient duration to meet diagnostic criteria for the disorder specified by the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM) published by the American Psychiatric Association; and (2) has resulted in a functional impairment that substantially interferes with or limits a consumer's role or functioning in family, school, or community activities. "Serious emotional disturbance" shall not include neurodevelopmental disorders, substance-related disorders, or conditions or problems classified in the current version of the DSM as "other conditions that may be a focus of clinical attention," unless those conditions co-occur with another diagnosable serious emotional disturbance.

"Service plan" means an individualized goal-oriented plan of services written in language understandable by the individual using the service and developed collaboratively by the individual and the organization.

"Staff" means people paid by the organization to perform duties and responsibilities defined in the organization's policies and procedures.

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441—24.2(225C) Standards for policy and procedures.

24.2(1) *Performance benchmark.* The organization has written policy direction for the organization and each service being accredited.

24.2(2) *Performance indicators.*

a. The organization has a policies and procedures manual with policy guidelines and administrative procedures for all organizational activities and services specific to its organization that addresses the standards in effect at the time of review.

b. The policies and procedures cover each benchmark and indicator in this chapter.

c. The policies and procedures manual is made available to all staff.

441—24.3(225C) Standards for organizational activities.

24.3(1) *Performance improvement system.*

a. Performance benchmark. The organization has a systematic, organizationwide, planned approach to designing, measuring, evaluating, and improving the level of its performance.

b. Performance indicators. The organization:

(1) Annually measures and assesses organizational activities and services accredited in this chapter.

(2) Gathers information from individuals using the services, from staff, and from family members.

(3) Implements an internal review of individual records for those services accredited under this chapter. For outpatient psychotherapy and counseling services, the organization:

1. Reviews the individual's involvement in and with treatment.

2. Ensures that treatment activities are documented and are relevant to the diagnosis or presenting problem.

(4) Reviews the organization's response to incidents reported under subrule 24.4(5) for necessity, appropriateness, effectiveness and prevention. This review includes analysis of incident data at least annually to identify any patterns of risk to the health and safety of consumers.

(5) Reviews the organization's response to any situation that poses a danger or threat to staff or to individuals using the services for necessity, appropriateness, effectiveness, and prevention.

(6) Identifies areas in need of improvement.

(7) Has a plan to address the areas in need of improvement. Where applicable, the organization establishes a plan to resolve the problem of patients missing appointments.

(8) Implements the plan and documents the results.

24.3(2) *Leadership.*

a. Performance benchmark. Organization leaders provide the framework for the planning, designing, directing, coordination, provision and improvement of services that are responsive to the individuals using the services and the community served by the organization.

b. Performance indicators.

(1) There are clearly articulated mission and values statements that are reflected in the long-range organizational plans and in organization policies.

(2) The annual and long-range budgeting process involves appropriate governing and managing levels of leadership and reflects the organization's mission and values. An independent auditor or other person as provided by law performs an annual financial audit.

(3) Individuals using the services or family members of individuals using the services are represented on the organization's governing board or on an advisory board.

(4) The organization's decision-making process, including policy decisions affecting the organization, reflects involvement of the various levels of leadership and responsiveness to staff.

(5) Organization leaders solicit input from leaders of the various community groups representing individuals served by the organization in designing responsive service delivery systems.

(6) Organization leaders develop and implement a service system appropriate to the needs of the individuals served by the organization.

(7) Organization leaders make educational information, resources, and service consultation available to community groups.

24.3(3) *Management information system.*

a. Performance benchmark. Information is obtained, managed, and used in an efficient and effective method to document, enhance, and improve organizational performance and service delivery.

b. Performance indicators.

(1) The organization has a system in place to maintain current individual-specific information documenting the provision and outcomes of services and treatments provided.

(2) The organization has a system in place to maintain the confidentiality and security of information that identifies specific individuals using the services, including mail, correspondence, and electronic files.

24.3(4) *Human resources.*

a. Performance benchmark. The organization provides qualified staff to support the organization's mission and facilitate the provision of quality services.

b. Performance indicators. The organization:

(1) Has a job description in the personnel file of each staff member that clearly defines responsibilities and qualifications.

(2) Has a process to verify qualifications of staff, including degrees, licenses, medication management training, and certification as required by the position, within 90 days of the staff person's employment. For staff hired after July 1, 2006, personnel files contain evidence that verification of professional licenses and college degrees at the bachelor's level or higher, as required by the position, was obtained from the primary source.

(3) Evaluates staff annually.

(4) Includes a plan for staff development for each staff member in the annual evaluation.

(5) Provides training and education to all staff relevant to their positions.

(6) Provides for approved training on child and dependent adult abuse reporter requirements to all organization staff who are mandatory abuse reporters. The organization documents in personnel records training on child and dependent adult abuse reporter requirements.

(7) Has staff members sign a document indicating that they are aware of the organization's policy on confidentiality and maintains these documents in the personnel files.

(8) Provides an initial orientation to new staff and documents this orientation in the employee's personnel file.

(9) Has mechanisms in place that afford staff the right to express concerns about a particular care issue or to file a grievance concerning a specific employment situation.

(10) Completes criminal and abuse record checks and evaluations as required in Iowa Code section 135C.33(5) before employment for any employee who meets with individuals using the services in the individuals' homes.

(11) Establishes and implements a code of ethics for all staff addressing confidentiality, individual rights, and professional and legal issues in providing services and documents in the personnel records that the code of ethics in effect at the time of review has been reviewed with each staff member.

24.3(5) *Organizational environment.*

a. Performance benchmark. The organization provides services in an organizational environment that is safe and supportive for the individuals being served and the staff providing services.

b. Performance indicators.

(1) The environment enhances the self-image of the individual using the service and preserves the individual's dignity, privacy, and self-development.

(2) The environment is safe and accessible and meets all applicable local, state, and federal regulations.

(3) The processes that service and maintain the environment and the effectiveness of the environment are reviewed within the organization's monitoring and improvement system.

(4) The organization establishes intervention procedures for behavior that presents significant risk of harm to the individual using the service or others. The interventions also ensure that the individual's rights are protected and that due process is afforded.

(5) The organization meets state and federal regulations in the way it implements the safe storage, provision, administration, and disposal of medication when used within the service.

(6) All toys and other materials used by children are clean and safe.

441—24.4(225C) Standards for services. Providers for the services set forth in subrules 24.4(9) through 24.4(13) shall meet the standards in subrules 24.4(1) through 24.4(8) in addition to the standards for the specific service. Providers of outpatient psychotherapy and counseling services shall also meet standards in subrules 24.4(1), 24.4(2), 24.4(4), 24.4(6), 24.4(7), and 24.4(8). Providers of emergency services or evaluation services shall meet the benchmark for the services they provide.

24.4(1) *Social history.*

a. Performance benchmark. The organization completes a social history for each individual served.

b. Performance indicators.

(1) The organization collects and documents relevant historical information and organizes the information in one distinct document.

(2) The social history includes:

1. Relevant information regarding the onset of disability.
2. Family, physical, psychosocial, behavioral, cultural, environmental, and legal history.
3. Developmental history for children.
4. Any history of substance abuse, domestic violence, or physical, emotional, or sexual abuse.

(3) Staff review and update the social history at least annually.

24.4(2) *Assessment.*

a. Performance benchmark. The organization develops a written assessment for each individual served. The assessment is the basis for the services provided to the individuals.

b. Performance indicators.

(1) The assessment includes information about the individual's current situation, diagnosis, needs, problems, wants, abilities and desired results, gathered with the individual's involvement.

(2) Staff solicit collateral provider information as appropriate to the individual situation in order to compile a comprehensive and full assessment.

(3) Staff base decisions regarding the level, type and immediacy of services to be provided, or the need for further assessment or evaluation, upon the analysis of the information gathered in the assessment.

(4) Staff complete an annual reassessment for each individual using the service and document the reassessment.

(5) Documentation supporting the diagnosis is contained in the individual's record. A diagnosis of intellectual disability is supported by a psychological evaluation conducted by a qualified professional. A diagnosis of developmental disability is supported by professional documentation. A determination of chronic mental illness is supported by a psychiatric or psychological evaluation conducted by a qualified professional.

24.4(3) *Individual service plan.*

a. Performance benchmark. Individualized, planned, and appropriate services are guided by an individual-specific service plan developed in collaboration with the individual using the service, staff, and significantly involved others as appropriate. Services are planned for and directed to where the individuals live, learn, work, and socialize.

b. Performance indicators.

(1) The service plan is based on the current assessment.

(2) The service plan identifies observable or measurable individual goals and action steps to meet the goals.

(3) The service plan includes interventions and supports needed to meet those goals with incremental action steps, as appropriate.

(4) The service plan includes the staff, people, or organizations responsible for carrying out the interventions or supports.

(5) Services defined in the service plan are appropriate to the severity level of problems and specific needs or disabilities.

(6) The plan reflects desired individual outcomes.

(7) Activities identified in the service plan encourage the ability and right of the individual using the service to make choices, to experience a sense of achievement, and to modify or continue participation in the treatment process.

(8) Staff monitor the service plan with review occurring regularly. At least annually, staff assess and revise the service plan to determine achievement, continued need, or change in goals or intervention methods. The review includes the individual using the service, with the involvement of significant others as appropriate.

(9) Staff develop a separate, individualized, anticipated discharge plan as part of the service plan that is specific to each service the individual receives.

(10) The service plan includes documentation of any rights restrictions, why there is a need for the restriction, and a plan to restore those rights or a reason why a plan is not necessary or appropriate.

24.4(4) *Documentation of service provision.*

a. Performance benchmark. Individualized and appropriate intervention services and treatments are provided in ways that support the needs, desires, and goals identified in the service plan, and that respect the rights and choices of the individual using the service.

b. Performance indicators.

(1) Staff document in the narrative the individual's participation in the treatment process.

(2) Responsible staff document the individual's progress toward goals, the provision of staff intervention, and the individual's response to those interventions.

(3) Documentation of service provision is in a legible, written format in accordance with organizational policies and procedures.

24.4(5) *Incident reports.*

a. Performance benchmark. The organization completes an incident report when organization staff first become aware that an incident has occurred.

b. Performance indicators.

(1) The organization documents the following information:

1. The name of the individual served who was involved in the incident.
2. The date and time the incident occurred.
3. A description of the incident.
4. The names of all organization staff and others who were present or responded at the time of the incident. (For confidentiality reasons, other individuals who receive services should be identified by initials or some other accepted means.)
5. The action the organization staff took to handle the situation.
6. The resolution of or follow-up to the incident.

(2) The staff who were directly involved at the time of the incident or who first became aware of the incident prepare and sign the incident report before forwarding it to the supervisor.

(3) Staff file a copy of the completed incident report in a centralized location and make a notation in the individual's file.

(4) Staff send a copy of the incident report to the individual's Medicaid targeted case manager or county case worker who is involved in funding the service and notify the individual's legal guardian within 72 hours of the incident.

24.4(6) *Confidentiality and legal status.*

a. Performance benchmark. Staff release medical and mental health information only when properly authorized.

b. Performance indicators.

(1) The organization obtains voluntary written authorization from the individual using the service, the individual's legal guardian, or other people authorized by law before releasing personal identifying information, medical records, mental health records, or any other confidential information.

(2) Staff complete voluntary written authorization forms in accordance with existing federal and state laws, rules, and regulations and maintain them in each individual file.

(3) Documentation regarding restrictions on the individual, such as guardianship, power of attorney, conservatorship, mental health commitments, or other court orders, is placed in the individual's record, if applicable.

24.4(7) *Service systems.*

a. Performance benchmark. The organization develops a clear description of each of the services offered. The organization develops an admission and discharge system of services. Staff coordinate services with other settings and providers.

b. Performance indicators.

(1) The organization has established and documented the necessary admission information to determine each individual's eligibility for participation in the service.

(2) Staff include verification in each individual's file that a service description was provided to the individual using the service and, when appropriate, to family or significant others.

(3) Continuity of services occurs through coordination among the staff and professionals providing services. Coordination of services through linkages with other settings and providers has occurred, as appropriate.

(4) Staff include a written discharge summary in each individual record at the time of discharge.

24.4(8) *Respect for individual rights.*

a. Performance benchmark. Each individual using the service is recognized and respected in the provision of services, in accordance with basic human, civil, and statutory rights.

b. Performance indicators.

(1) Staff provide services in ways that respect and enhance the individual's sense of autonomy, privacy, dignity, self-esteem, and involvement in the individual's own treatment. Staff take language barriers, cultural differences, and cognitive deficits into consideration and make provisions to facilitate meaningful individual participation.

(2) Staff inform individuals using the service and, when appropriate, family and significant others of their rights, choices, and responsibilities.

(3) The organization has a procedure established to protect the individuals using the service during any activities, procedure or research that requires informed consent.

(4) The organization verifies that individuals using the service and their guardians are informed of the process to express questions, concerns, complaints, or grievances about any aspect of the individual's service, including the appeal process.

(5) The organization provides the individuals and their guardians the right to appeal the application of policies, procedures, or any staff action that affects the individual using the service. The organization has established written appeal procedures and a method to ensure that the procedures and appeal process are available to individuals using the service.

(6) All individuals using the service, their legal representatives, and other people authorized by law have access to the records of the individual using the service in accordance with state and federal laws and regulations.

24.4(9) *Case management services.* "Case management services" means those services established pursuant to Iowa Code section 225C.20.

a. Performance benchmark. Case management services link individuals using the service to service agencies and support systems responsible for providing the necessary direct service activities and coordinate and monitor those services.

b. Performance indicators.

(1) Staff clearly define the need for case management and document it annually.

(2) At a minimum, the team is composed of the individual using the service, the case manager, and providers or natural supports relevant to the individual's service needs. The team may also include family members, at the discretion of the individual using the service.

(3) The team works with the individual using the service to establish the service plan that guides and coordinates the delivery of the services.

(4) The case manager advocates for the individual using the service.

(5) The case manager coordinates and monitors the services provided to the individual using the service.

(6) Documentation of contacts includes the date, the name of the individual using the service, the name of the case manager, and the place of service.

(7) The case manager holds individual face-to-face meetings at least quarterly with the individual using the service.

(8) Case managers do not provide direct services. Individuals using the service are linked to appropriate resources, which provide necessary direct services and natural supports.

(9) Individuals using the service participate in developing an individualized crisis intervention plan that includes natural supports and self-help methods.

(10) Documentation shows that individuals using the service are informed about their choice of providers as provided in the county management plan.

(11) Within an accredited case management program, the average caseload is no more than 45 individuals per each full-time case manager. The average caseload of children with serious emotional disturbance is no more than 15 children per full-time case manager.

(12) The case manager communicates with the team and then documents in the individual's file a quarterly review of the individual's progress toward achieving the goals.

24.4(10) *Day treatment services.* "Day treatment" means an individualized service emphasizing mental health treatment and intensive psychosocial rehabilitation activities designed to increase the individual's ability to function independently or facilitate transition from residential placement. Staff use individual and group treatment and rehabilitation services based on individual needs and identified behavioral or mental health issues.

a. Performance benchmark. Individuals using the service who are experiencing a significantly reduced ability to function in the community are stabilized and improved by the receipt of psychosocial rehabilitation, mental health treatment services, and in-home support services, and the need for residential or inpatient placement is alleviated.

b. Performance indicators.

(1) Individuals using the service participate with the organizational staff in identifying the problem areas to be addressed and the goals to be achieved that are based on the individual's need for services.

(2) Individuals using the service receive individualized services designed to focus on those identified mental health or behavioral issues that are causing significant impairment in their day-to-day functioning.

(3) Individuals who receive intensive outpatient and day treatment services receive a comprehensive and integrated schedule of recognized individual and group treatment and rehabilitation services.

(4) Individuals using the service and staff review their progress in resolving problems and achieving goals on a frequent and regular basis.

(5) Individuals using the service receive services appropriate to defined needs and current risk factors.

(6) Individuals using the service receive services from staff who are appropriately qualified and trained to provide the range and intensity of services required by the individual's specific problems or disabilities. A mental health professional provides or directly supervises the provision of treatment services.

(7) Individuals using the service participate in discharge planning that focuses on coordinating and integrating individual, family, and community and organization resources.

(8) Family members of individuals using the service are involved in the planning and provision of services, as appropriate and as desired by the individual.

(9) Individuals using the service participate in developing a detailed psychiatric crisis intervention plan that includes natural supports and self-help methods.

24.4(11) *Intensive psychiatric rehabilitation services.* "Intensive psychiatric rehabilitation services" means services designed to restore, improve, or maximize level of functioning, self-care, responsibility, independence, and quality of life; to minimize impairments, disabilities, and disadvantages of people who have a disabling mental illness; and to prevent or reduce the need for services in a hospital or residential setting. Services focus on improving personal capabilities while reducing the harmful effects of psychiatric disability, resulting in an individual's recovering the ability to perform a valued role in society.

a. Performance benchmark. Individuals using the service who are experiencing a significantly reduced ability to function in the community due to a disability are stabilized and experience role recovery by the receipt of intensive psychiatric rehabilitation services.

b. Performance indicators.

(1) Individuals using the service receive services from staff who meet the definition of intensive psychiatric rehabilitation practitioner. The intensive psychiatric rehabilitation supervisor has at least a bachelor's degree in a human services field and 60 hours of training in intensive psychiatric rehabilitation.

(2) Individuals using the service receive four to ten hours per week of recognized psychiatric rehabilitation services. All services are provided for an identified period.

(3) Whenever possible, intensive psychiatric rehabilitative services are provided in natural settings where individuals using the service live, learn, work, and socialize.

(4) Significantly involved others participate in the planning and provision of services as appropriate and as desired by the individual using the service.

(5) Individuals using the service participate in developing a detailed psychiatric crisis intervention plan that includes natural supports and self-help methods.

(6) A readiness assessment is initially completed with staff to assist the individual in choosing a valued role and environment. The readiness assessment culminates in a score that documents the individual's motivational readiness.

(7) During the readiness development phase, staff document monthly in the individual's file changes in the individual's motivational readiness to choose valued roles and environments.

(8) During the goal-choosing phase, staff and the individual identify personal criteria, describe alternative environments, and choose the goal. These activities are documented in the individual's file.

(9) During the goal-achieving phase, the functional assessment and resource assessment are completed. Skill programming or skill teaching takes place. These activities are documented in the individual's file.

(10) During goal keeping, individuals using the service participate in discharge planning that focuses on coordinating and integrating individual, family, community, and organization resources for successful community tenure and the anticipated end of psychiatric rehabilitation services. Staff document increases in skill acquisition and skill competency.

(11) Staff document any positive changes in environmental status, such as moving to a more independent living arrangement, enrolling in an education program, getting a job, or joining a community group.

(12) On an ongoing basis and at discharge, staff or the individual using the service documents the level of individual satisfaction with intensive psychiatric rehabilitation services in each individual's file.

24.4(12) *Supported community living services.* "Supported community living services" means those services provided to individuals with a mental illness, mental retardation, or developmental disability to enable them to develop supports and learn skills that will allow them to live, learn, work and socialize in the community. Services are individualized, need- and abilities-focused, and organized according to the following components: outreach to appropriate support or treatment services; assistance and referral in meeting basic human needs; assistance in housing and living arrangements; crisis intervention and assistance; social and vocational assistance; the provision of or arrangement for personal, environmental, family, and community supports; facilitation of the individual's identification and development of natural support systems; support, assistance, and education to the individual's family and to the community; protection and advocacy; and service coordination.

These services are to be provided by organizational staff or through linkages with other resources and are intended to be provided in the individual's home or other natural community environment where the skills are learned or used. Supported community living is not part of an organized mental health support or treatment group, drop-in center, or clubhouse. Skill training groups may be one of the activities in the service plan and part of supported community living. Skill training groups cannot stand alone as a supported community living service.

a. Performance benchmark. Individuals using the service live, learn, work, and socialize in the community.

b. Performance indicators.

(1) Individuals receive services within their home and community setting where the skills are learned or used.

(2) At intake, the individuals using the service participate in a functional assessment to assist in defining areas of service need and establishing a service plan. Staff summarize the findings of the functional assessment in a narrative that describes the individual's current level of functioning in the areas of living, learning, working, and socialization. Staff review functional assessments on a regular basis to determine progress.

(3) Individuals using the service receive skill training and support services directed to enabling them to regain or attain higher levels of functioning or to maximize functioning in the current goal areas.

(4) Services are delivered on an individualized basis in the place where the individual using the service lives or works.

(5) Documentation that steps have been taken to encourage the use of natural supports and develop new ones is in the individual file.

(6) Individuals using the service participate in developing a detailed individualized crisis intervention plan that includes natural supports and self-help methods.

24.4(13) *Partial hospitalization services.* "Partial hospitalization services" means an active treatment program providing intensive group and individual clinical services within a structured therapeutic environment for individuals who are exhibiting psychiatric symptoms of sufficient severity to cause significant impairment in day-to-day functioning. Short-term outpatient crisis stabilization and rehabilitation services are provided to avert hospitalization or to transition from an acute care setting. Services are supervised and managed by a mental health professional, and psychiatric consultation is routinely available. Clinical services are provided by a mental health professional.

a. Performance benchmark. Individuals who are experiencing serious impairment in day-to-day functioning due to severe psychiatric distress are enabled to remain in their community living situation through the receipt of therapeutically intensive milieu services.

b. Performance indicators.

(1) Individuals using the service and staff mutually develop an individualized service plan that focuses on the behavioral and mental health issues and problems identified at admission. Goals are based on the individual's need for services.

(2) Individuals using the service receive clinical services that are provided and supervised by mental health professionals. A licensed and qualified psychiatrist provides psychiatric consultation and medication services.

(3) Individuals using the service receive a comprehensive schedule of active, planned, and integrated psychotherapeutic and rehabilitation services provided by qualified professional staff.

(4) Individuals using the service receive group and individual treatment services that are designed to increase their ability to function independently.

(5) Individuals using the service are involved in the development of an anticipated discharge plan that includes linkages to family, provider, and community resources and services.

(6) Individuals using the service have sufficient staff available to ensure their safety, to be responsive to crisis or individual need, and to provide active treatment services.

(7) Individuals using the service receive services commensurate with current identified risk and need factors.

(8) Support systems identified by individuals using the service are involved in the planning and provision of services and treatments as appropriate and desired by the individual using the service.

(9) Individuals using the service participate in developing a detailed psychiatric crisis intervention plan that includes natural supports and self-help methods.

24.4(14) *Outpatient psychotherapy and counseling services.* "Outpatient psychotherapy and counseling services" means a dynamic process in which the therapist uses professional skills, knowledge and training to enable individuals using the service to realize and mobilize their strengths and abilities, take charge of their lives, and resolve their issues and problems. Psychotherapy services may be individual, group, or family, and are provided by a person meeting the criteria of a mental health professional or by a person with a master's degree or an intern working on a master's degree in a mental health field who is directly supervised by a mental health professional.

a. Performance benchmark. Individuals using the service realize and mobilize their own strengths and abilities to take control of their lives in the areas where they live, learn, work, and socialize.

b. Performance indicators.

(1) Individuals using the service are prepared for their role as partners in the therapeutic process at intake where they define their situations and evaluate those factors that affect their situations.

(2) Individuals using the service establish desired problem resolution at intake during the initial assessment.

(3) Psychiatric services other than psychopharmacological services are available from the organization as needed by the individual using the service.

(4) Psychopharmacological services are available from the organization as needed.

(5) Staff document mutually agreed-upon treatment goals during or after each session. A distinct service plan document is not required.

(6) Staff document mutually agreed-upon supports and interventions during or after each session. A distinct service plan document is not required.

(7) Staff document in the progress notes the individual's status at each visit and the reasons for continuing or discontinuing services. A distinct discharge summary document is not required.

(8) Any assignment of activities to occur between sessions is documented in the following session's documentation.

(9) Individuals using the service who have a chronic mental illness participate in developing a detailed psychiatric crisis intervention plan that includes natural supports and self-help methods.

(10) The record documents that the organization follows up on individuals who miss appointments.

24.4(15) *Emergency services.* "Emergency services" means crisis services that provide a focused assessment and rapid stabilization of acute symptoms of mental illness or emotional distress and are available and accessible, by telephone or face-to-face, on a 24-hour basis. The clinical assessment and psychotherapeutic services are provided by a person who has training in emergency services and who is a mental health professional or has access to a mental health professional, at least by telephone.

Services may be provided by a person who holds a master's degree in a mental health field including, but not limited to, psychology, counseling and guidance, psychiatric nursing, psychiatric rehabilitation, or social work; or a person who holds a bachelor's degree in a human service discipline with five years' experience providing mental health services or human services; or a psychiatric nurse who has three years of clinical experience in mental health. A comprehensive social history is not required for this treatment.

a. Performance benchmark. Individuals using the service receive emergency services when needed that provide a focused assessment and rapid stabilization of acute symptoms of mental illness or emotional distress.

b. Performance indicators.

(1) Individuals using the service can access 24-hour emergency services by telephone or in person.

(2) Information about how to access emergency services is publicized to facilitate availability of services to individuals using the service, family members, and the public.

(3) Individuals using the service receive assessments and services from either a mental health professional or from personnel who meet the requirements above and are supervised by a mental health professional. Psychiatric consultation is available, if needed.

(4) Individuals using the service receive intervention commensurate with current identified risk factors.

(5) Significantly involved others are involved as necessary and appropriate to the situation and as desired by the individual using the service.

(6) Individuals using the service are involved in the development of postemergency service planning and resource identification and coordination.

(7) Staff document contacts in a narrative format and maintain them in a central location that will allow timely response to the problems presented by the individual using the service.

(8) Timely coordination of contacts with relevant professionals is made.

24.4(16) *Evaluation services.* "Evaluation services" means screening, diagnosis and assessment of individual and family functioning needs, abilities, and disabilities, and determining current status and functioning in the areas of living, learning, working, and socializing.

a. Performance benchmark. Individuals using the service receive comprehensive evaluation services that include screening, diagnosis, and assessment of individual or family functioning, needs and disabilities.

b. Performance indicators.

(1) Evaluations include screening, diagnosis, and assessment of individual or family functioning, needs, abilities, and disabilities.

(2) Evaluations consider the emotional, behavioral, cognitive, psychosocial, and physical information as appropriate and necessary.

(3) Evaluations includes recommendations for services and need for further evaluations.

(4) Mental health evaluations are completed by a person who meets the criteria of a mental health professional, or a person with a master's degree who is license-eligible and supervised by a mental health professional, or an intern of a master's or doctorate program who is supervised by a mental health professional.

[**ARC 3855C**, IAB 6/20/18, effective 8/1/18]

441—24.5(225C) Accreditation. The commission shall make all decisions involving issuance, denial, or revocation of accreditation. This accreditation shall delineate all categories of service the organization is accredited to provide. Although an organization may have more than one facility or service site, the

commission shall issue only one accreditation notice to the organization, except as provided in paragraph 24.5(5)*"f."*

24.5(1) *Organizations eligible for accreditation.* The commission accredits the following organizations:

a. Case management providers.

b. Community mental health centers.

c. Supported community living providers.

d. Mental health service providers.

24.5(2) *Application and renewal procedures.* An applicant for accreditation shall submit Form 470-3005, Application for Accreditation, to the Division of Behavioral, Developmental, and Protective Services, Department of Human Services, Fifth Floor, Hoover State Office Building, 1305 East Walnut, Des Moines, Iowa 50319-0114.

a. The application shall be signed by the organization's chief executive officer and the chairperson of the governing body and shall include the following information:

(1) The name and address of the applicant organization.

(2) The name and address of the chief executive officer of the applicant organization.

(3) The type of organization and specific services for which the organization is applying for accreditation.

(4) The targeted population groups for which services are to be provided, as applicable.

(5) The number of individuals in each of the targeted population groups to be served, as applicable.

(6) Other information related to the standards as requested by division staff.

b. Organizations that have received an initial 270-day accreditation and have not provided services by the end of the 270 days shall have their accreditation lapse for that specific service. This lapse of accreditation shall not be considered a denial. New applications may be submitted that include the waiting list of individuals to be served along with specific timelines of when the services will begin.

c. An organization in good standing may apply for an add-on service.

24.5(3) *Application review.* Upon receipt of an application, Form 470-3005, the division shall review the materials submitted to determine whether the application is complete and request any additional material as needed. Survey reviews shall commence only after the organization has submitted all application material.

a. For a new organization, staff may initially conduct a desk audit or on-site visit to review the organization's mission, policies, procedures, staff credentials, and program descriptions.

b. The division shall review organizational services and activities as determined by the accreditation category. This review may include audits of case records, administrative procedures, clinical practices, personnel records, performance improvement systems and documentation, and interviews with staff, individuals, boards of directors, or others deemed appropriate, consistent with the confidentiality safeguards of state and federal laws.

c. A team shall make an on-site visit to the organization. The division shall not be required to provide advance notice to the provider of the on-site visit for accreditation.

d. The on-site team shall consist of designated members of the division staff. At the division's discretion, the team may include provider staff of other providers, individuals, and others deemed appropriate.

e. The team shall survey the organization and the services indicated on the accreditation application in order to verify information contained in the application and ensure compliance with all applicable laws, rules, and regulations. At the time of a one-year recertification visit, the team shall review the services that did not receive three-year accreditation.

f. The team shall review case records and personnel records to see how the organization implements each of the indicators in the standards. If the documentation is not found in the records, the organization shall show, at the time the division staff is on site, documentation of how the indicator was accomplished.

g. When an organization subcontracts with agencies to provide services, on-site reviews shall be done at each subcontracting agency to determine if each agency meets all the requirements in this chapter. The accreditation is issued to the organization.

h. At the end of the survey, the team leader shall lend an exit review. Before the close of the on-site review, the organization must provide the team leader any documentation that demonstrates how the organization has met these standards for services.

i. The accreditation team leader shall send a written report of the findings to the organization within 30 working days after completion of the accreditation survey.

j. Organizations required to develop a corrective action and improvement plan pursuant to subrule 24.5(4)*"a"* shall submit the plan to the division within 30 working days after the receipt of a report issued as a result of the division's survey review. The action plan shall include specific problem areas cited, corrective actions to be implemented by the organization, dates by which each corrective measure shall be completed, and quality assurance and improvement activities to measure and ensure continued compliance.

k. Quality assurance staff shall review and approve the corrective action and improvement plan before making an accreditation recommendation to the commission.

l. The division shall offer technical assistance to organizations applying for first-time accreditation. Following accreditation, any organization may request technical assistance from the division to bring into conformity those areas found in noncompliance with this chapter's requirements. If multiple deficiencies are noted during a survey, the commission may also require that technical assistance be provided to an organization, as staff time permits, to assist in implementation of an organization's corrective action plan. Renewal applicants may be provided technical assistance as needed, if staff time permits.

24.5(4) *Performance outcome determinations.* There are three major areas addressed in these standards: policies and procedures, organizational activities, and services, as set forth in rules 441—24.2(225C), 24.3(225C), and 24.4(225C). Each rule contains standards, with a performance benchmark and performance indicators for each standard. Each of the applicable standards for the three areas (policy and procedures, organizational activities, and services) shall be reviewed.

a. Quality assurance staff shall determine a performance compliance level based on the number of indicators found to be in compliance.

(1) For service indicators, if 25 percent or more of the files reviewed do not comply with the requirements for a performance indicator, then that indicator is considered out of compliance and corrective action is required.

(2) Corrective action is required when any indicator under policies and procedures or organizational activities is not met.

b. In the overall rating, the performance rating for policy and procedures shall count as 15 percent of the total, organizational activities as 15 percent of the total, and services as 70 percent of the total.

(1) Each of the three indicators for policy and procedures has a value of 5 out of a possible score of 15.

(2) Each of the 34 indicators for organizational activities has a value of .44 out of a possible score of 15.

(3) Each service has a separate weighting according to the total number of indicators applicable for that service, with a possible score of 70, as follows:

Service	Number of indicators	Value of each indicator
Case management	51	1.37
Day treatment	48	1.46
Intensive psychiatric rehabilitation	51	1.37
Supported community living	45	1.55
Partial hospitalization	48	1.46
Outpatient psychotherapy and counseling	35	2.00
Emergency	8	8.75
Evaluation	4	17.50

c. Quality assurance staff shall determine a separate score for each service to be accredited. When an organization offers more than one service under this chapter, there shall be one accreditation award for all the services based upon the lowest score of the services surveyed.

24.5(5) *Accreditation decisions.* The division shall prepare all documents with a final recommendation regarding accreditation to be presented at the commission meeting. The division shall mail to all commission members summary reports of the on-site service review or desk review and a final recommendation concerning accreditation on each application to be processed at the next commission meeting.

If the commission approves accreditation, Form 470-3006, Notice of Action-Approval, shall be issued which states the duration of the accreditation and the services that the organization is accredited to provide. If the commission denies or revokes accreditation, Form 470-3008, Notice of Action-Denial, shall be issued which states the reasons for the denial.

a. Initial 270-day accreditation. This type of accreditation may be granted to a new organization. The commission shall base the accreditation decision on a report by the division that:

(1) The organization has an approved policies and procedures manual that includes job descriptions.

(2) Staff assigned to the positions meet the qualifications in the standards and the policies and procedures of the organization.

b. Three-year accreditation. An organization or service is eligible for this type of accreditation if it has achieved an 80 percent or higher performance compliance level. The organization may be required to develop and submit a plan of corrective action and improvement that may be monitored either by written report or an on-site review.

c. One-year accreditation. An organization is eligible for this type of accreditation when multiple and substantial deficiencies exist in specific areas causing compliance levels with performance benchmarks and indicators to fall between 70 percent and 79 percent, or when previously required corrective action plans have not been implemented or completed. The organization must submit a corrective action plan to correct and improve specific deficiencies and overall levels of functioning. Quality assurance staff shall monitor this plan through on-site reviews, written reports and the provision of technical assistance.

d. Probational 180-day accreditation. An organization is eligible for probational 180-day accreditation instead of denial when the overall compliance level is from 60 to 69 percent, and pervasive and serious deficiencies exist; or when corrective action plans previously required as a result of a one-year accreditation have not been implemented or completed. The commission may downgrade organizations with a one-year or three-year accreditation to the probational 180-day accreditation when one or more complaints are founded.

All deficiencies must be corrected by the time of the follow-up on-site survey at the conclusion of the provisional period. After this survey, the organization shall meet the standards for accreditation for a one-year accreditation, or the commission shall deny accreditation.

e. Add-on service accreditation. When the on-site review of the add-on service results in a score comparable to the overall organization's score at the time of the most recent accreditation, the organization shall have the add-on accreditation date coincide with the overall accreditation date of the organization. If the add-on service on-site review results in a lower score and lower accreditation

decision, division staff shall conduct another on-site review for that add-on service when the add-on service accreditation expires.

f. Special terms.

(1) When an organization subcontracts with more than one agency, the length of accreditation shall be determined individually.

(2) The accreditation period for services that have deemed status according to rule 24.6(225C) shall coincide with the period awarded by the national accrediting body or the certification for home-and community-based services.

(3) New or add-on services that meet the requirements for accreditation shall receive an initial 270-day accreditation for that individual service. The term of accreditation shall be determined individually. At the time of recertification of the new add-on service, recommendation may be made to coincide with the term of accreditation for the other services of that organization that are accredited by the commission.

(4) An organization must notify the division when there are changes in its ownership, structure, management, or service delivery.

g. Extensions. The division may grant an extension to the period of accreditation if there has been a delay in the accreditation process that is beyond the control of the organization, the division, or the commission; or the organization has requested an extension to permit the organization to prepare and obtain approval of a corrective action plan. The division shall establish the length of the extension on a case-by-case basis.

h. Denial of accreditation. An emergency commission meeting may be called to consider denial or revocation of accreditation.

(1) Accreditation shall be denied when there are pervasive and serious deficiencies that put individuals at immediate risk or when the overall compliance level falls to 59 percent or below. Under such circumstances no corrective action report shall be required.

(2) When one or more complaints are received, quality assurance staff shall complete an investigation and submit a report to the commission. If any of the complaints are substantiated and the commission determines that there is a pervasive or serious deficiency, the commission may deny accreditation.

(3) An organization whose accreditation has been denied or revoked shall not be approved for any service for at least six months from the notice of decision denying or revoking accreditation.

(4) If the organization disagrees with any action or failure to act in regard to the notice of decision to deny accreditation to the organization, the organization has the right to appeal in accordance with 441—Chapter 7.

24.5(6) *Nonassignability.* Accreditation shall not be assignable to any other organization or provider. Any person or other legal entity acquiring an accredited facility for the purpose of operating a service shall make an application as provided in subrule 24.5(2) for a new certificate of accreditation. Similarly, any organization having acquired accreditation and desiring to alter the service philosophy or transfer operations to different premises must notify the division in writing 30 calendar days before taking action in order for the division to review the change.

24.5(7) *Discontinuation.*

a. Discontinued organization. A discontinued organization is one that has terminated all of the services for which it has been accredited. Accreditation is not transferable between organizations.

(1) An organization shall notify the division in writing of any sale, change in business status, closure, or transfer of ownership of the business at least 30 calendar days before the action.

(2) The organization shall be responsible for the referral and placement of individuals using the services, as appropriate, and for the preservation of all records.

b. Discontinued service. An organization shall notify the division in writing of the discontinuation of an accredited or certified service at least 30 calendar days before the service is discontinued.

(1) Notice of discontinuation of a service shall not be initiated during the 30 days before the start of a survey. Once a survey has begun, all services shall be considered in determining the organization's accreditation score.

(2) The organization shall be responsible for the referral and placement of individuals using the services, as appropriate, and for the preservation of all records.

441—24.6(225C) Deemed status. The commission shall grant deemed status to organizations accredited by a recognized national, not-for-profit, accrediting body when the commission determines the accreditation is for similar services. The commission may also grant deemed status for supported community living services to organizations that are certified under the Medicaid home- and community-based services (HCBS) mental retardation waiver.

24.6(1) *National accrediting bodies.*

a. The national accrediting bodies currently recognized as meeting division criteria for possible deeming are:

1. Joint Commission on Accreditation of Healthcare Organizations (JCAHO).
2. The Commission on Accreditation of Rehabilitation Facilities (CARF).
3. The Council on Quality and Leadership in Supports for People with Disabilities (The Council).
4. Council on Accreditation of Services for Families and Children (COA).

b. The accreditation credentials of these national bodies must specify the type of organization, programs, and services that these bodies accredit and include targeted population groups, if appropriate.

c. Deemed status means that the division is accepting an outside body's review, assessment, and accreditation of an organization's functioning and services. Therefore, the accrediting body doing the review must be assessing categories of organizations and types of programs and services corresponding to those described under this chapter. An organization that has deemed status must adhere to and be accountable for the rules in this chapter.

d. When an organization that is nationally accredited requests deemed status for services not covered by the national body's standards but covered under this chapter, the division shall accredit those services. Division staff shall provide technical assistance to organizations with deemed status as time permits.

24.6(2) *Application for deemed status.*

a. To apply for deemed status, the organization shall submit Form 470-3332, Application and Letter of Agreement, and copies of the latest survey report and accreditation certificate, documentation of specific programming policies and procedures for populations being served, and credentials for staff providing services to populations served.

b. The division shall not accept an application for deemed status once the division has begun an on-site visit. The organization shall complete the accreditation process.

24.6(3) *Requirements for deemed status.* To be eligible for deemed status, the organization shall:

a. Be currently accredited by a recognized national accrediting body for services as defined in subrule 24.6(1); or

b. Be currently accredited for supported community living under the Medicaid HCBS mental retardation waiver pursuant to 441—subrule 77.37(14). If individuals with mental illness are served, the organization must submit verification of the training and credentials of the staff to show that its staff can meet the needs of the individuals served.

c. Require the supported community living staff to have the same supervisor as the HCBS/MR program.

d. Require staff for the program being deemed to have the training and credentials needed to meet the needs of the person served.

e. Require staff to meet the incident reporting requirements in subrule 24.4(5).

24.6(4) *Granting of deemed status.* When the commission grants deemed status, the accreditation period shall coincide with the period awarded by the national accrediting body or the certification for home- and community-based services. However, under no circumstances shall the commission award accreditation for longer than three years.

24.6(5) *Reservations.* When deemed status is granted, the commission and the division reserve rights to the following:

a. To have division staff conduct on-site reviews for those organizations applying for deemed status which the division has not previously accredited.

b. To have division staff do joint site visits with the accrediting body, attend exit conferences, or conduct focused follow-behind visits as determined to be appropriate in consultation with the national accrediting organization and the provider organization.

c. To be informed of and to investigate all complaints that fall under this chapter's jurisdiction according to the process in rule 441—24.7(225C). The division shall report findings to the national accrediting body.

d. To review and act upon deemed status when:

(1) Complaints have been founded, or

(2) The organization's national accreditation status expires without renewal, or

(3) The national accrediting body downgrades or withdraws the organization's status.

24.6(6) *Continuation of deemed status.*

a. The organization shall send a copy of Form 470-3332, Application and Letter of Agreement, along with a copy of the application for renewal to the national accrediting body at the same time as application is made to a national accrediting body.

b. HCBS staff shall furnish to the division copies of the letter notifying a provider of a forthcoming recertification for organizations deemed for supported community living under the HCBS mental retardation waiver.

c. Following the on-site review by a national accrediting body, the organization shall send the division a copy of the cover sheet and the national accrediting body report within 30 calendar days from the date that the organization receives the documents. If a corrective action plan is required, the organization shall send the division a copy of all correspondence and documentation related to the corrective action.

d. HCBS staff shall furnish the division with copies of HCBS certification reports and any corrective action required by HCBS within 30 calendar days after HCBS staff complete the report or the organization completes required corrective action.

441—24.7(225C) Complaint process. The division shall receive and record complaints by individuals using the services, employees, any interested people, and the public relating to or alleging violations of applicable requirements of the Iowa Code or administrative rules.

24.7(1) *Submittal of complaint.* The complaint may be delivered personally or by mail to the Division of Behavioral, Developmental, and Protective Services, Department of Human Services, Hoover State Office Building, Fifth Floor, 1305 East Walnut, Des Moines, Iowa 50319-0114, or by telephone (515)281-5874.

a. The division shall assist individuals in making a complaint as needed or requested.

b. The information received should specifically state the basis of the complaint. The division shall keep the name of the complainant confidential to the extent allowed by law.

24.7(2) *Review of complaint.* Upon receipt of a complaint, the division shall make a preliminary desk review of the complaint to determine an appropriate response. That response may include notifying the person who submitted the complaint that there is no basis for a review, referring the complaint to another investigative body, or making a determination to do a full investigation.

24.7(3) *Investigation of complaint.* If the division concludes that the complaint is reasonable, has merit, and is based on a violation of rules in this chapter, it may make an investigation of the organization. The division may investigate complaints by an office audit or by an on-site investigation. The division shall give priority for on-site investigations to instances when individuals using the service are in immediate jeopardy.

a. If a decision is made to conduct an on-site investigation, the on-site review does not require advance notice to the organization. The division shall notify the chief executive officer and board chairperson of the organization involved before or at the commencement of the on-site investigation that the division has received a complaint.

b. The division shall give the organization an opportunity to informally present a position regarding allegations in the complaint. The organization may submit the position in writing within five working days following the on-site visit or present it in a personal conference with division staff.

c. The division shall submit a written report by certified mail to the chief administrative officer of the organization and the chairperson of the board of directors within 20 working days after completion of the investigation.

d. The report shall indicate whether the complaint was or was not substantiated, the basis for the substantiation or nonsubstantiation, the specific rules violated, and a recommendation for corrective action with time lines specified in the report.

e. The date of delivery shown by the certified mail stub shall constitute the date of official notice.

24.7(4) *Review by commission.* When individuals receiving services are in immediate jeopardy, the commission may call an emergency meeting to make a decision on possible revocation or denial of accreditation.

a. To the extent allowed by Iowa Code section 21.5, the commission may review the complaint and investigation report in a closed meeting. The action taken by the commission shall be voted upon in the reconvened public meeting and entered into the official record of commission minutes.

b. If the complaint is substantiated, the commission make take actions deemed appropriate, which may include shortening the term of accreditation, requiring a corrective action plan, or suspending or revoking an organization's accreditation, depending on the severity of the substantiated complaint.

c. The division shall inform the complainant and the organization by certified mail of the findings and actions taken by the commission. The date of delivery shown by the certified mail stub shall constitute the date of official notice.

24.7(5) *Corrective action plan.* When the commission acts to suspend or revoke accreditation, there will be no corrective action plan. In other instances, if the complaint is substantiated, the organization shall submit a corrective action plan to the division within 20 calendar days after receiving the commission's decision. This plan must respond to violations cited and commission requirements and include time lines, internal monitoring systems, and performance improvement planning.

Failure of the organization to respond within 20 calendar days with an acceptable corrective action plan that addresses the organization's plan of correction following a substantiated investigation or complaint may of itself constitute the basis for revocation or suspension of accreditation. The commission shall determine the appropriate action based on the information submitted. The division shall notify the organization of any action the commission takes.

441—24.8(225C) Appeal procedure. An appeal may be filed using the procedure identified in 441—Chapter 7. Notice of an appeal shall be sent to Appeals Section, Department of Human Services, Hoover State Office Building, Fifth Floor, 1305 East Walnut, Des Moines, Iowa 50319-0114, within 30 calendar days of the written decision from the commission.

441—24.9(225C) Exceptions to policy. Requests for exceptions to the policies in this chapter shall follow the policies and procedures in the department's general rule on exceptions to policy at 441—1.8(17A,217).

These rules are intended to implement Iowa Code chapter 225C.

441—24.10 to **24.19** Reserved.

DIVISION II
CRISIS RESPONSE SERVICES

PREAMBLE

The department of human services in consultation with the mental health and disability services commission has established this set of standards to be met by all providers of crisis response services.

[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

441—24.20(225C) Definitions.

"Action plan" means a written plan developed for discharge in collaboration with the individual receiving crisis response services to identify the problem, prevention strategies, and management tools for future crises.

"Crisis assessment" means a face-to-face clinical interview to ascertain an individual's current and previous level of functioning, potential for dangerousness, physical health, and psychiatric and medical condition. The crisis assessment becomes part of the individual's action plan.

"Crisis incident" means an occurrence leading to physical injury or death, or an occurrence resulting from a prescription medication error, or an occurrence triggering a report of child or dependent adult abuse.

"Crisis response services" means short-term individualized crisis stabilization services which follow a crisis screening or assessment and which are designed to restore the individual to a prior functional level.

"Crisis response staff" means a person trained to provide crisis response services in accordance with rule 441—24.24(225C).

"Crisis screening" means a process to determine what crisis response service is appropriate to effectively resolve the presenting crisis.

"Crisis stabilization community-based services" or *"CSCBS"* means short-term services designed to de-escalate a crisis situation and stabilize an individual following a mental health crisis and provided where the individual lives, works or recreates.

"Crisis stabilization residential services" or *"CSRS"* means a short-term alternative living arrangement designed to de-escalate a crisis situation and stabilize an individual following a mental health crisis and is provided in organization-arranged settings of no more than 16 beds.

"Department" means the department of human services.

"Dispatch" means the function within crisis line operations to coordinate access to crisis care.

"Face-to-face" means services provided in person or utilizing telehealth in conformance with the federal Health Insurance Portability and Accountability Act (HIPAA) privacy rules.

"Family support peer specialist" means the same as defined in rule 441—25.1(331).

"Informed consent" means the same as defined in rule 441—24.1(225C).

"Mental health crisis" means a behavioral, emotional, or psychiatric situation which results in a high level of stress or anxiety for the individual or persons providing care for the individual and which cannot be resolved without intervention.

"Mental health professional" means the same as defined in Iowa Code section 228.1.

"Mobile response" means a mental health service which provides on-site, face-to-face mental health crisis services for an individual experiencing a mental health crisis. Crisis response staff providing mobile response have the capacity to intervene wherever the crisis is occurring, including but not limited to the individual's place of residence, an emergency room, police station, outpatient mental health setting, school, recovery center or any other location where the individual lives, works, attends school, or socializes.

"Peer support services" means a service provided by a peer support specialist, including but not limited to education and information, individual advocacy, family support groups, crisis response, and respite to assist individuals in achieving stability in the community.

"Peer support specialist" means the same as defined in rule 441—25.1(331).

"Physical health" means any chronic or acute health factors that need to be addressed during crisis delivery services.

"Qualified prescriber" means a practitioner or other staff following the instruction of a practitioner as defined in Iowa Code section 155A.3 and a physician assistant or advanced registered nurse practitioner operating under the prescribing authority granted in Iowa Code section 147.107.

"Restraint" means the application of physical force or the use of a chemical agent or mechanical device for the purpose of restraining the free movement of an individual's body to protect the individual, or others, from immediate harm.

"Rights restriction" means limitations not imposed on the general public in the areas of communications, mobility, finances, medical or mental health treatment, intimacy, privacy, type of work, religion, and place of residence.

"Self-administered medication" means the process where a trained staff member observes an individual inject, inhale, ingest or, by any other means, take medication following the instructions of a qualified prescriber.

"Stabilization plan" means a written short-term strategy used to stabilize a crisis and developed by a mental health professional, in collaboration with the crisis response staff and with the involvement and consent of the individual or the individual's representative.

"Staff-administered medication" means the direct application of a prescription drug, whether by injection, inhalation, ingestion, or any other means, to the body of an individual by a qualified prescriber or authorized staff following instructions of a qualified prescriber.

"Telehealth" is the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration. Technologies include videoconferencing, the Internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications.

"Treatment summary" means a written summarization of the treatment and action plan at the point of an individual's discharge or transition to another service.

"Twenty-four-hour crisis line" means a crisis line providing information and referral, counseling, crisis service coordination, and linkages to crisis screening and mental health services 24 hours a day.

"Twenty-four-hour crisis response" means services are available 24 hours a day, 365 days a year, providing access to crisis screening and assessment and linkage to mental health services.

"Twenty-three-hour observation and holding" means a level of care provided for up to 23 hours in a secure and protected, medically staffed, psychiatrically supervised treatment environment.

"Warm line" means a telephone line staffed by individuals with lived experience who provide nonjudgmental, nondirective support to an individual who is experiencing a personal crisis.
[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

441—24.21(225C) Standards for crisis response services. An organization may be accredited to provide any one or all of the identified crisis response services. An organization seeking crisis response service accreditation shall comply with the general standards within this division and additional standards for each specific service.
[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

441—24.22(225C) Standards for policies and procedures. Policies and procedures manuals contain policy guidelines and administrative procedures for all activities and services and address the standards in rule 441—24.2(225C).
[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

441—24.23(225C) Standards for organizational activities.

24.23(1) The organization shall meet the standards in subrules 24.3(1) through 24.3(5).

24.23(2) The organization shall describe the staffing structure that details how staff are utilized to provide the specific crisis stabilization services in rules 441—24.32(225C) through 441—24.39(225C).
[**ARC 1660C**, IAB 10/15/14, effective 12/1/14; **ARC 3057C**, IAB 5/10/17, effective 7/1/17]

441—24.24(225C) Standards for crisis response staff. All crisis response staff shall meet the qualifications described in this rule. Additional staff requirements are described in each service.

24.24(1) *Performance benchmark.* Qualified crisis response staff provide crisis response services.

24.24(2) *Performance indicators.*

a. One or more of the following qualifications are met:

(1) A mental health professional as defined in Iowa Code section 228.1.

(2) A bachelor's degree with 30 semester hours or equivalent in a human services field (including, but not limited to, psychology, social work, nursing, education) and a minimum of one year of experience in behavioral or mental health services.

(3) A law enforcement officer with a minimum of two years of experience in the law enforcement officer's field.

(4) An emergency medical technician (EMT) with a minimum of two years of experience in the EMT's field.

(5) A peer support specialist with a minimum of one year of experience in behavioral or mental health services.

(6) A family support peer specialist with a minimum of one year of experience in behavioral or mental health services.

(7) A registered nurse with a minimum of one year of experience in behavioral or mental health services.

(8) A bachelor's degree in a non-human services-related field, associate's degree, or high school diploma (or equivalency) with a minimum of two years of experience in behavioral or mental health services, and 30 hours of crisis and mental health in-service training (in addition to the required 30 hours of department-approved training).

b. Documentation in staff records to verify satisfactory completion of department-approved training including:

(1) A minimum of 30 hours of department-approved crisis intervention and training.

(2) A posttraining assessment of competency is completed.

[**ARC 1660C**, IAB 10/15/14, effective 12/1/14; **ARC 3057C**, IAB 5/10/17, effective 7/1/17]

441—24.25(225C) Standards for services.

24.25(1) *Standard for eligibility.* An eligible recipient is an individual experiencing a mental health crisis or emergency where a mental health crisis screening is needed to determine the appropriate level of care.

24.25(2) *Confidentiality and legal status.* Standards in subrule 24.4(6) are met.

24.25(3) *Service systems.* Standards in subparagraphs 24.4(7)*"b"*(1) to (3) are met.

24.25(4) *Respect for individual rights.* Standards in subrule 24.4(8) are met.

[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

441—24.26(225C) Accreditation. The administrator for the division of mental health and disability services shall determine whether to grant, deny or revoke the accreditation of the centers and services as determined in Iowa Code section 225C.6(1)*"c."*

24.26(1) The organization shall meet the standards of subrule 24.5(1), with the addition of crisis response service organizations.

24.26(2) The organization shall meet the standards in subrules 24.5(2) and 24.5(3).

24.26(3) Performance outcome determinations are as follows:

a. Quality assurance staff shall determine a performance compliance level based on the number of indicators found to be in compliance.

(1) For service indicators, if 25 percent or more of the files reviewed do not comply with the requirements for a performance indicator, that indicator is considered out of compliance and corrective action is required.

(2) Corrective action is required when any indicator under policies and procedures or activities is not met.

b. In the overall rating, the performance rating for policies and procedures shall count as 15 percent of the total, activities as 15 percent of the total, and services as 70 percent of the total.

(1) Each of the three indicators for policies and procedures has a value of 5.0 out of a possible score of 15.

(2) Each of the 34 indicators for activities has a value of .44 out of a possible score of 15.

(3) Each service has a separate weighting according to the total number of indicators applicable for that service, with a possible score of 70, as follows:

c. Quality assurance staff shall determine a separate score for each service to be accredited. When an organization offers more than one service under this chapter, there shall be one accreditation award for all the services based upon the lowest score of the services surveyed.

Service	Number of Indicators	Value of Each Indicator
24-hour crisis response	19	3.9
Crisis evaluation	20	3.5
24-hour crisis line	23	3.0
Warm line	20	3.5
Mobile response	18	3.9
23-hour observation and holding	44	1.6
Crisis stabilization, community-based	39	1.8
Crisis stabilization, residential	50	1.4

24.26(4) The organization shall meet the standards in subrules 24.5(5) to 24.5(7).
[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

441—24.27(225C) Deemed status. The department shall grant deemed status to organizations accredited by a recognized national, not-for-profit, accrediting body when the department determines the accreditation is for similar services. The organization shall fulfill the standards described in subrules 24.6(1) to 24.6(6). The national accrediting bodies currently recognized as meeting division criteria for possible deeming are:

1. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO).
2. The Commission on Accreditation of Rehabilitation Facilities (CARF).
3. The Council on Quality and Leadership in Supports for People with Disabilities (The Council).
4. The Council on Accreditation of Services for Families and Children (COA).
5. The American Association of Suicidology (AAS).
6. Contact USA.

[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

441—24.28(225C) Complaint process. The department shall receive and record complaints by individuals using services, employees, any interested people, and the public relating to or alleging violations of applicable requirements of the Iowa Code or administrative rules in accordance with the standards described in rule 441—24.7(225C).
[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

441—24.29(225C) Appeal procedure. The department shall receive appeals according to the process in rule 441—24.8(225C).
[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

441—24.30(225C) Exceptions to policy. The department shall receive exceptions to policy meeting the standards in rule 441—24.9(225C).
[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

441—24.31(225C) Standards for individual crisis response services. Crisis response services provided to children and youth include coordination with parents, guardians, family members, natural supports, and service providers and with other systems such as education, juvenile justice and child welfare.

Crisis response services for individuals who have co-occurring or multi-occurring diagnoses focus on the integration and coordination of treatment services, and supports necessary to stabilize the individual, without regard to which condition is primary. Crisis response services are not to be denied due to the presence of a co-occurring substance abuse condition or developmental or neurodevelopmental disability.
[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

441—24.32(225C) Crisis evaluation. Crisis evaluation consists of two components: crisis screening and crisis assessment.

24.32(1) *Crisis screening.* The purpose of crisis screening is to determine the presenting problem and appropriate level of care.

a. Performance benchmark. Crisis screening includes a brief assessment of suicide lethality, substance use, alcohol use and safety needs. Crisis screening can be provided through contact with crisis response staff and through communication with the individual.

b. Performance indicators.

(1) Crisis response staff are trained in crisis screening.

(2) A uniform process for crisis screening and referrals is outlined in policies and procedures.

(3) Crisis screening records are kept in individual files.

24.32(2) *Crisis assessment.* The purpose of crisis assessment is to determine the precipitating factors of the crisis, the individual and family functioning needs, and the diagnosis if present and to initiate a stabilization plan and discharge plan. A licensed mental health professional conducts a crisis assessment within 24 hours of an individual's admission to a crisis response service.

a. Assessment requirements. The crisis assessment includes:

(1) Action plan.

(2) Active symptoms of psychosis.

(3) Alcohol use.

(4) Coping ability.

(5) History of trauma.

(6) Impulsivity or absence of protective factors.

(7) Intensity and duration of depression.

(8) Lethality assessment.

(9) Level of external support available to the individual.

(10) Medical history.

(11) Physical health.

(12) Prescription medication.

(13) Crisis details.

(14) Stress indicators and level of stress.

(15) Substance use.

b. Performance benchmark. Individuals receive comprehensive assessment by a mental health professional to determine the appropriate level of care.

c. Performance indicators.

(1) Written policies and procedures describe a uniform process for assessment, referrals and record documentation.

(2) Mental health professionals as defined in Iowa Code section 228.1(6) will complete assessments.

(3) Information collected is sufficient to determine the appropriate level of care.

(4) Assessment results are explained to the individual and family or guardian when appropriate.

(5) The individual's strengths, preferences and needs are included in an action plan. The family or guardian may receive a copy of an action plan with a signed release.

[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

441—24.33(225C) Twenty-four-hour crisis response. The purpose of 24-hour crisis response is to provide access to crisis screening and assessment to de-escalate and stabilize the crisis. When the assessment indicates, a stabilization plan is developed to support the individual's return to a prior level of functioning. Twenty-four-hour crisis response staff link the individual to appropriate services. Crisis response staff provide service to individuals of any age.

24.33(1) *Performance benchmark.* Individuals in crisis have the ability to access crisis response services, including, but not limited to, crisis screening, crisis assessment and stabilization in the least restrictive level of care appropriate.

24.33(2) *Performance indicators.*

a. Information on how to access 24-hour crisis response is publicized to facilitate availability of services to individuals using the service, family members and the public.

b. Individuals accessing the service receive crisis screening and crisis response services from appropriate crisis response staff.

c. Crisis screening is available and accessible face-to-face, using telephone or Web-based options, 24 hours a day, 365 days a year.

d. A mental health professional is available for crisis assessment and consultation 24 hours a day, 365 days a year. The mental health professional has access to a qualified prescriber for consultation.

e. The staffing pattern and schedule is documented.

f. The integration and coordination of care is documented in the individual's record.

g. The discharge, action and follow-up plans are documented in the individual's record, and copies of the plans are provided to the individual. The family or guardian may receive a copy with a signed release.

[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

441—24.34(225C) Twenty-four-hour crisis line. A 24-hour crisis line provides counseling, crisis service coordination, information and referral, linkage to services and crisis screening. Crisis line staff are qualified to provide crisis stabilization services pursuant to subrule 24.24(2).

24.34(1) *Performance benchmark.* Crisis screening, counseling, crisis service coordination and referrals are provided to individuals in crisis.

24.34(2) *Performance indicators.*

a. The crisis line service is available 24 hours a day, 365 days a year.

b. Policies are in place regarding how the crisis line is answered live, when to utilize the hold feature, the use of queue systems and triage of calls.

c. Policies and procedures govern the use of technology, including telephonic and Internet capability in the service delivery structure, quality assurance, data integrity and confidentiality.

d. Procedures are in place for ensuring the quality of the crisis line, including monitoring calls and corrective action plans.

e. The crisis line is an integrated component of the crisis response service system; the crisis line is answered in an organization setting by trained crisis response staff.

f. Policies define collaborative efforts and triage procedure between the mobile outreach teams, law enforcement and emergency services.

g. Policies are in place to ensure follow-up contacts are provided within 24 hours of a crisis call for all risk cases. The crisis line integrates follow-up into all crisis service contacts.

h. The crisis line utilizes standardized call center software with the capability to track:

(1) Date and time of answered call, topic of call, crisis screening provided, referral made, hold time, and demographics of call.

(2) Number of contacts, including terminated and lost calls.

i. Policies and procedures describe a uniform process of crisis screening and training for crisis line staff.

j. Training includes crisis screening tools, lethality assessment, crisis counseling, cultural competence, crisis service coordination, and information and referral.

k. Twenty-four-hour access to a mental health professional is required.

[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

441—24.35(225C) Warm line. A peer-operated warm line is a service individuals can access to talk with someone with lived experience with mental, behavioral health and trauma issues. The line provides a resource for individuals experiencing emotional distress.

24.35(1) *Performance benchmark.* A warm line provides nonjudgmental listening, nondirective assistance, information, referral, and triage when appropriate.

24.35(2) *Performance indicators.*

a. Policies are in place regarding how the warm line is answered live, placing callers on hold and when appropriate to use a queue system.

b. Policies and procedures are in place for standard collection of demographics, the presented reason for calling and outcome of call.

c. Policies and procedures are in place for crisis screening and when to triage a caller to a higher level of service.

d. Data collection includes call answer times, duration of calls, and number of calls dropped, lost or terminated.

e. Policies and procedures describe the staffing pattern and schedule.

f. Warm-line staff can receive calls remotely through telephones or computers or within an organization.

g. Staff qualifications and training for peer support specialists and family support peer specialists are required.

h. Twenty-four-hour access to a mental health professional is required.

[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

441—24.36(225C) Mobile response. Crisis response staff provide on-site, in-person intervention for individuals experiencing a mental health crisis. The mobile response staff provide crisis response services in the individual's home or at locations in the community. Staff work in pairs to ensure staff safety and the safety of the individual served. A single staff member may respond if another person who meets one of the criteria listed in paragraph 24.24(2)*"a"* will be available on site. Twenty-four-hour access to a mental health professional is required.

24.36(1) *Performance benchmark.* Mobile response services are delivered to individuals in crisis in a timely manner.

24.36(2) *Performance indicators.*

a. Mobile response staff are dispatched immediately after crisis screening has determined the appropriate level of care. If the mobile response staff already are responding to another call, staff explain to the caller that there may be a delay in receiving a mobile response and offer an alternative response.

b. Mobile response staff have face-to-face contact with the individual in crisis within 60 minutes from dispatch. If the mobile response staff are responding to another request, there may be a delay in receiving mobile response and an alternative response should be provided.

c. Data is collected to track and trend response time from initial dispatch, the time to respond to dispatch when a team is already in response; diversion from or admission to hospitals, correctional facilities and other crisis response services. The data for each fiscal year is reported to the department within 60 days of the close of the fiscal year.

d. When an action plan is developed, a copy is sent within 24 hours, with the individual's signed consent, to service providers, the individual and others as appropriate.

e. The following information is documented in the individual's service record:

(1) Triage and referral information.

(2) Reduction in the level of risk present in the crisis situation.

(3) Coordination with other mental health resources.

(4) Names and affiliation of all individuals participating in the mobile response.

f. A follow-up appointment with the individual's preferred provider will be made, and mobile response staff will follow up with the individual and document contact or attempt to contact on a periodic basis until the appointment takes place.

[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

441—24.37(225C) Twenty-three-hour crisis observation and holding. Twenty-three-hour crisis observation and holding services may be a stand-alone service or embedded within a crisis stabilization residential service. Twenty-three-hour crisis observation and holding services are designed for individuals who need short-term crisis intervention in a safe environment less restrictive than hospitalization. This level of service is appropriate for individuals who require protection or when an individual's ability to cope in the community is severely compromised and it is expected the crisis can

be resolved in 23 hours. Twenty-three-hour crisis observation and holding services include, but are not limited to, treatment, medication administration, meeting with extended family or significant others, and referral to appropriate services. Twenty-three-hour crisis observation and holding chairs can be utilized.

24.37(1) *Admission criteria.* The services may be provided if any of the following admission criteria are met:

a. There are indications the symptoms can be stabilized and an alternative treatment can be initiated within a 23-hour period.

b. The presenting crisis cannot be safely evaluated or managed in a less restrictive setting, or no such setting is available.

c. The individual does not meet inpatient criteria, and it is determined a period of observation assists in the stabilization and prevention of symptom exacerbation.

d. Further evaluation is necessary to determine the individual's service needs.

e. There is an indication of actual or potential danger to self or others as evidenced by a current threat or ideation.

f. There is a loss of impulse control leading to life-threatening behavior and other psychiatric symptoms requiring stabilization in a structured, monitored setting.

g. The individual is experiencing a crisis demonstrated by an abrupt or substantial change in normal life functioning brought on by a specific cause, sudden event or severe stressor.

24.37(2) *Staffing requirements.*

a. A designated medical director or administrator is responsible for the management and operation of the organization or facility.

b. Registered nurse practitioners and physician assistants have at least two years of mental health experience.

c. At least one mental health professional is available for consultation 24 hours a day, 365 days a year.

d. A mental health professional as defined in Iowa Code section 228.1(6) provides mental health services appropriate to the individual's needs.

e. Crisis response staff are on duty 24 hours a day.

f. A registered nurse is available on site 24 hours a day.

24.37(3) *Twenty-three-hour observation and holding safety.*

a. Performance benchmark. An incident report is created when staff are notified an incident has occurred.

b. Performance indicators.

(1) The incident report documents:

1. The name of the individual or individuals who were involved in the incident.
2. Date and time of occurrence of the incident.
3. A description of the incident.
4. Names and signatures of all staff present at the time of the incident.
5. The action taken by the staff.
6. The resolution or follow-up to the incident.

(2) A copy of the incident report is kept in a centralized file and a copy is given to the individual, the mental health and disability services region, and the individual's parent or guardian when appropriate.

24.37(4) *Service requirements.*

a. Performance benchmark. A treatment summary is provided to the individual and the individual's treatment team when applicable.

b. Performance indicators. The minimum treatment summary requirements include:

(1) Action plan.
(2) Crisis assessment, including challenges and strengths.
(3) Course and progress of the individual with regard to each identified challenge.
(4) Evaluation of the individual's mental status to inform ongoing placement and support decisions.
(5) Recommendations and arrangements for further service needs.
(6) Signature of the mental health professional.

(7) Treatment interventions.

c. Performance benchmark. The individual using this service is provided a safe, secure observation and holding service in a location meeting the needs of the individual and in the least restrictive setting.

d. Performance indicators.

(1) Individuals give informed consent.

(2) Treatment providers, family members and other natural supports as appropriate are contacted within 23 hours of the individual's admission.

(3) Written policies and procedures cover medication administration, storage and documentation.

(4) Individual records include, but are not limited to, a treatment summary and verification of individual choice.

(5) The 23-hour crisis observation and holding facility is a welcoming and comfortable environment conducive to recovery.

(6) The 23-hour crisis observation and holding is primarily used as a diversion from hospital level of care.

(7) Communication attempts and contact with the individual's team will be documented.

(8) A follow-up appointment with the individual's preferred provider will be made, and crisis response staff will follow up with the individual and document contact or attempt to contact on a periodic basis until the appointment takes place.

(9) There are written policies and procedures of how to document and track discharge locations.

(10) The actual number of individuals served within the 23-hour period is documented. Individual treatment records contain reasons why individuals stay beyond the 23-hour period.

(11) Readmission data and length of time between admissions are tracked for data trend reports.

e. Performance benchmark. Policies and procedures address the additional safety standards for 23-hour crisis and observation services.

f. Performance indicators.

(1) Service compliance is documented regarding state fire marshal rules and fire ordinances and applicable local health, fire, occupancy code, and safety regulations.

(2) Based on standards used for public facilities, all food and drink is clean, wholesome, free from spoilage, and stored and served in a manner safe for human consumption.

(3) Doors must not be locked from the inside. The use of door locks is as approved by the fire marshal and professional staff.

(4) Twenty-three-hour observation and holding services have an emergency preparedness plan to describe the process for an individual to continue receiving services during a disaster including, but not limited to, cases of severe weather or fire.

g. Performance benchmark. Policies and procedures address the cleanliness of the 23-hour observation and holding service.

h. Performance indicators.

(1) Services provide a safe, clean, well-ventilated, properly heated environment in good repair and free from vermin.

(2) An individual's resting or sleeping area includes:

1. A sturdily constructed bed or comfortable chair.
2. A sanitized mattress protected with a clean mattress pad, or sanitized chair.
3. Curtains or blinds are on bedroom windows.
4. Available clean linen.
5. Doors or partitions for privacy.
6. Right to privacy is respected.

(3) Bathrooms include items necessary for personal hygiene and personal privacy.

1. A safe supply of hot and cold running water which is potable.
2. Clean towels, electric hand dryers or paper towel dispensers, and an available supply of toilet paper and soap.
3. Natural or mechanical ventilation capable of removing odors.

4. Tubs or showers have slip-proof surfaces.

5. Partitions with doors which provide privacy if a bathroom has multiple toilet stools.

6. Toilets, wash basins, and other plumbing or sanitary facilities are maintained in good operating condition.

7. Privacy in bathrooms for male and female individuals.

i. Performance benchmark. Personal rights are acknowledged.

j. Performance indicator. The following are allowed:

(1) Areas in which an individual may be alone when appropriate.

(2) Areas for private conversations with others.

(3) Secure space for personal belongings.

(4) Personal clothing is allowed in accordance with organization policy.

k. Performance benchmark. Policies and procedures address health and safety standards.

l. Performance indicators.

(1) An emergency preparedness plan is designed to provide effective utilization of available resources during a disaster event including, but not limited to, cases of severe weather or fire.

(2) Services comply with rule 441—24.39(225C).

(3) There are written policies on safety.

(4) Seclusion is not used.

(5) Mechanical or chemical restraints are not used at any time.

(6) The smokefree air Act, Iowa Code chapter 142D, is followed.

[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

441—24.38(225C) Crisis stabilization community-based services (CSCBS). The goal of CSCBS is to stabilize the individual within the community. CSCBS is designed as a voluntary service for individuals in need of a safe, secure location that is less intensive and restrictive than an inpatient hospital. Individuals receive CSCBS services including, but not limited to, psychiatric services, medication, counseling, referrals, peer support and linkage to ongoing services. The duration for CSCBS is expected to be less than five days.

24.38(1) *Eligibility.* To be eligible, an individual must:

a. Be determined appropriate for the service by mental health assessment; and

b. Be determined not to need inpatient acute hospital psychiatric services.

24.38(2) *Staffing requirements.*

a. A designated director or administrator is responsible for the management and operation of the CSCBS.

b. At least one licensed nurse practitioner, physician assistant, or psychiatrist is available for consultation 24 hours a day, 365 days a year.

c. Mental health professionals with expertise appropriate to the individual's needs provide services.

d. Contact between the individual and a mental health professional occurs at least one time a day.

e. Additional services are provided by crisis response staff at a minimum of one hour per day, including, but not limited to, skill building, peer support or family support peer services. The goal of CSCBS is to stabilize the individual within the community. CSCBS is designed for voluntary services for individuals in need of a safe, secure location that is less intensive and restrictive than an inpatient hospital.

f. Crisis response staff must be awake and attentive 24 hours a day.

24.38(3) *Performance benchmark.* The individual using CSCBS is provided safe, secure and structured crisis stabilization services in the least restrictive location meeting the needs of the individual. The CSCBS can be for youth aged 18 and under or adults aged 18 and older.

24.38(4) *Performance indicators.*

a. The individual can provide consent for treatment providers, family members and other natural supports to be contacted within 24 hours of admission.

b. Daily crisis stabilization services include, at minimum, daily contact with a mental health professional and one hour of additional crisis stabilization services from crisis response staff.

c. The numbers of days an individual receives crisis stabilization services are documented. The documentation records specific reasons for the delivery of services beyond five days.

d. Individual records are maintained to document the following:

(1) Daily contact with a mental health professional.

(2) Additional services provided including, but not limited to, skill building, peer support or family support peer services.

(3) Medication record.

e. Individual choice is verified including, but not limited to, treatment participation and discharge plan options.

f. Readmission data is tracked, including an analysis of data trends looking at effectiveness, and appropriate corrective action taken. The information is documented in the performance improvement system files.

24.38(5) *Crisis stabilization incident reporting.*

a. Performance benchmark. An incident report is filed when staff are notified an incident has occurred.

b. Performance indicators.

(1) The incident report documents:

1. The name of the individual involved in the incident.
2. Date and time the incident occurred.
3. A description of the incident.
4. Names and signatures of all staff present at the time of the incident.
5. The action the staff took to handle the situation.
6. The resolution or follow-up to the incident.

(2) A copy of the incident report is kept in a centralized file and a copy given to the individual, the mental health and disability services region, and the parent or guardian when appropriate.

24.38(6) *Service requirements.*

a. Stabilization plan. The individual in crisis is involved collaboratively in all aspects of crisis stabilization services including, but not limited to, admission, treatment planning, intervention, and discharge. The involvement of family members and others is encouraged.

Within 24 hours of an individual's admission to crisis stabilization services, a written short-term stabilization plan is developed, with the involvement and consent of the individual, and is reviewed frequently to assess the need for the individual's continued placement in CSCBS. At a minimum, this plan includes:

(1) Criteria for discharge, including referrals and linkages to appropriate services and coordination with other systems.

(2) Description of any physical disability and any accommodations necessary to provide the same or equal services and benefits as those afforded nondisabled individuals.

(3) Evidence of input by the individual, including the individual's signature.

(4) Goal statement. Goals are consistent with the individual's needs and projected duration of service delivery and include objectives which build on strengths and are stated in terms allowing measurement of progress.

(5) Rights restrictions.

(6) Names of all other persons participating in the development of the plan.

(7) Specification of treatment responsibilities and methods.

b. Performance benchmark. A stabilization plan is completed within 24 hours of the individual's admittance.

c. Performance indicators.

(1) Individual records include a written short-term stabilization plan developed with the involvement and consent of the individual within 24 hours of admittance and reviewed frequently to assess the need for continued placement in CSCBS.

(2) Individual records indicate a crisis stabilization plan is completed within the 24-hour time frame.

(3) Reasons for crisis stabilization plans not meeting the criteria are documented.

(4) A follow-up appointment with the individual's preferred provider will be made, and crisis response staff will follow up with the individual and document contact or attempt to contact on a periodic basis until the appointment takes place.

24.38(7) *Treatment summary.* Prior to the individual's discharge from CSCBS, a treatment summary is completed. A copy of the summary is provided to the individual and shared with the individual's treatment team of providers, if applicable.

a. Contents. At a minimum, the treatment summary includes:

(1) Course and progress of the individual with regard to each identified problem.

(2) Documented note of a mental health professional contact one time daily.

(3) Evolution of the mental status to inform ongoing placement and support decisions.

(4) Final assessment, including general observations and significant findings of the individual's condition initially while services were being provided and at discharge.

(5) Recommendations and arrangements for further service needs.

(6) Signature of the mental health professional.

(7) Stabilization plan.

(8) Reasons for termination of service.

(9) Treatment interventions.

b. Performance benchmark. A treatment summary is completed during the length of stay in CSCBS.

c. Performance indicators.

(1) Records include a written treatment summary developed with the involvement of the individual. A copy of the summary is provided upon discharge.

(2) Incidents in which a treatment plan was not completed within the length of stay and any corrective action necessary to alleviate this issue are documented.

24.38(8) *Health and safety.*

a. Performance benchmark. Emergency preparedness policies and procedures include health and safety measures.

b. Performance indicators.

(1) Emergency preparedness plans are designed to provide effective utilization of available resources for care to continue during a disaster event including, but not limited to, cases of severe weather or fire.

(2) Crisis services comply with rule 441—24.39(225C).

[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

441—24.39(225C) Crisis stabilization residential services (CSRS). Crisis stabilization residential services are short-term services provided in facility-based settings of no more than 16 beds. The goal of CSRS is to stabilize and reintegrate the individual back into the community. Crisis stabilization residential services are designed for voluntary individuals who are in need of a safe, secure environment less intensive and restrictive than an inpatient hospital. Crisis stabilization residential services have the capacity to serve more than two individuals at a time. Crisis stabilization residential services can be for youth aged 18 and younger or adults aged 18 and older. Youth and adults cannot be housed in the same facility setting. Facilities licensed by the department of inspections and appeals for other services would have to comply with the provisions of Iowa Administrative Code rule 481—57.50(135C) for operating another business or activity in the facility.

24.39(1) *Eligibility.* To be eligible, an individual must:

a. Be an adult aged 18 or older or a youth aged 18 or under.

b. Be determined appropriate for the service by a mental health assessment; and

c. Be determined to not need inpatient acute hospital psychiatric services.

24.39(2) *Staffing requirements.*

a. A designated director or administrator is responsible for the management and operation of the CSRS of no more than 16 beds.

b. At least one licensed mental health professional is available for consultation 24 hours a day, 365 days a year.

c. Crisis stabilization residential services are provided by a mental health professional with expertise appropriate to the individual's needs.

d. Each individual has contact with a mental health professional at least one time a day.

e. Each individual has a minimum of one hour per day of additional services provided by crisis response staff including, but not limited to, skill building, peer support or family support peer services; or other therapeutic programming.

f. Awake and attentive staffing 24 hours a day, 365 days a year is provided.

24.39(3) *Performance benchmark.* The individual is provided safe, secure and structured crisis stabilization services in the least restrictive location meeting the individual's needs.

24.39(4) *Performance indicators.*

a. Individual's consent is documented, and treatment providers, family members and other natural supports are contacted within 24 hours of admission.

b. A comprehensive mental health assessment is completed within 24 hours of admission.

c. Daily crisis stabilization includes, at minimum, daily contact with a mental health professional and one hour of additional crisis stabilization service.

d. The length of stay is expected to be less than five days.

e. The number of days an individual receives crisis stabilization services is documented. The documentation records specific reasons for lengths of stay beyond five days.

f. Records include:

(1) Stabilization plan.

(2) Medication record.

(3) Treatment summary.

(4) Daily contact with a mental health professional.

g. Additional services provided include, but are not limited to, skill building, peer support or family support peer services.

h. Individual choice is verified including, but not limited to, treatment participation and discharge plan options.

i. Data of readmission is tracked including an analysis of data trends, looking at effectiveness, and appropriate corrective action. The information is documented in the performance improvement system.

j. Documentation tracks that the youth's education needs are met with educational services received in the CSRS, and an action plan is in place to return the youth to school upon discharge.

24.39(5) *Crisis stabilization incident reporting.*

a. Performance benchmark. An incident report is completed when staff are notified an incident has occurred.

b. Performance indicators.

(1) The incident report documents:

1. The name of the individual who was involved in the incident.
2. Date and time of occurrence of the incident.
3. A description of the incident.
4. Names and signatures of all staff present at the time of the incident.
5. The action staff took to handle the situation.
6. The resolution or follow-up to the incident.

(2) A copy of the incident report is maintained in a centralized file and a copy given to the individual, the mental health and disability services region, and the parent or guardian when appropriate.

24.39(6) *Service requirements.*

a. Stabilization plan. The individual is involved collaboratively in all aspects of crisis stabilization services including, but not limited to, admission, treatment planning, intervention, and discharge. The involvement of family members and others is encouraged.

Within 24 hours of admission to CSRS, a written short-term stabilization plan is developed, with the involvement and consent of the individual, and reviewed frequently to assess the need for continued placement in CSRS. At a minimum, this plan includes:

(1) Criteria for discharge, including referrals and linkages to appropriate services and coordination with other systems.

(2) Description of any physical disability and accommodations necessary to provide the same or equal services and benefits as those afforded nondisabled individuals.

(3) Evidence of input by the individual, including the individual's signature.

(4) Goal statement.

(5) Goals consistent with needs and projected length of stay.

(6) Objectives that are built on strengths and allow measurement of progress.

(7) Rights restrictions.

(8) Signatures of all participating in the development of the plan.

(9) Specification of treatment responsibilities and methods.

b. Performance benchmark. A stabilization plan is completed within 24 hours of admittance.

c. Performance indicators.

(1) Records include a written short-term stabilization plan developed with the involvement and consent of the individual within 24 hours of admission and is reviewed frequently to assess the need for continued placement in CSRS.

(2) Records indicating a stabilization plan has been completed within the 24-hour time frame are maintained.

(3) Reasons the stabilization plan does not meet the criteria is documented.

(4) A follow-up appointment with the individual's preferred provider will be made, and crisis response staff will follow up with the individual and document contact or attempt to contact on a periodic basis until the appointment takes place.

24.39(7) *Treatment summary.* Prior to discharge, a treatment summary is provided and a copy shared with the individual and treatment team as appropriate.

a. Contents. At a minimum, this treatment summary includes:

(1) Course and progress regarding each identified problem.

(2) Documentation of daily contact with a mental health professional.

(3) Impact on placement and support decisions.

(4) Assessment.

(5) Action plan.

(6) Stabilization plan.

(7) Treatment interventions.

(8) Reasons for termination of service.

(9) Signature of the mental health professional.

b. Performance benchmark. A treatment summary is completed during the individual's length of stay in CSRS.

c. Performance indicators.

(1) Records include a written treatment summary developed with the involvement and consent of the individual.

(2) An individual receives a copy of the treatment summary upon discharge.

(3) Corrective action steps are documented when treatment plans are not completed within the length of stay.

24.39(8) *Health and safety.*

a. Performance benchmarks.

(1) Emergency preparedness policies and procedures include health and safety measures.

(2) Crisis stabilization services meet all applicable local, state and federal regulations.

(3) Medication administration and documentation standards in rule 441—24.40(225C) are documented.

b. Performance indicators.

(1) Health and fire safety inspections.

1. Documentation includes Iowa fire marshal rules and fire ordinances, local health, fire, occupancy code, and safety regulations.

2. Standards for public facilities guide food and beverage safety, nutrition standards, and safe storage of all consumable products.

3. Crisis stabilization residential services comply with rule 441—24.40(225C).

(2) Emergency preparedness. Emergency preparedness policies are designed to provide effective utilization of available resources for continuation during a disaster event, including, but not limited to, cases of severe weather or fire.

(3) The facility is safe, clean, well-ventilated, and a properly heated environment in good repair and free from vermin.

(4) Bedrooms include:

1. A sturdily constructed bed.

2. A sanitized mattress protected with a clean mattress pad.

3. A designated space in proximity to the sleeping area for personal possessions including clothing.

4. Curtains or window blinds on bedroom windows.

5. Available clean linens.

(5) Sleeping areas include:

1. Doors for privacy.

2. Partitioning and placement of furniture to provide privacy.

3. Rooms accommodate no more than two per room. Single room dimensions are at least 80 square feet not including closets. Dual occupancy rooms are at least 120 square feet not including closets.

4. Personal belongings and personal touches in the rooms are defined within CSRS policy.

5. Respect by staff for an individual's right to privacy.

(6) Personal hygiene and privacy tools are provided:

1. A safe supply of hot and cold running water which is potable.

2. Clean towels, electric hand dryers or paper towel dispensers, and an available supply of toilet paper and soap.

3. Natural or mechanical ventilation capable of removing odors.

4. Tubs or showers with slip-proof surfaces.

5. Partitions with doors which provide privacy if a bathroom has multiple toilet stools.

6. Toilets, wash basins, and other plumbing or sanitary facilities are in good operating condition.

7. Privacy in bathrooms for male and female individuals.

(7) Federal laws regarding smoking on property are recognized and followed.

(8) The following is provided:

1. Areas in which an individual may be alone when appropriate.

2. Areas for private conversations with others.

3. A secure space for personal belongings.

c. Housekeeping. Maintenance of living quarters and day-to-day housekeeping activities are clearly defined in writing and a part of the orientation. Staff assistance and equipment are provided as needed.

d. Clothing.

(1) Personal clothing is allowed in accordance with CSRS policy.

(2) Clothing may be washed with provided laundry mechanisms.

e. Religion/culture. Rights to religion and culture include:

(1) The opportunity to participate in religious activities and services in accordance with the individual's faith or of a minor individual's parent(s) or guardian.

(2) Arrange for transportation to religious activities when appropriate per CSRS policy.

f. Smoking. The smokefree air Act, Iowa Code chapter 142D, is included in the CSRS policy.

[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

441—24.40(225C) Medication—administration, storage and documentation. This rule sets forth medication requirements for 23-hour crisis observation and holding, crisis stabilization community-based services, and crisis stabilization residential services.

24.40(1) *Performance benchmark.* Policies and procedures ensure prescription and over-the-counter drugs are administered or self-administered safely and properly in accordance with federal, state and local laws and regulations. Medication is administered by a qualified prescriber or an individual following the instructions of a qualified prescriber. Medication storage is maintained in accordance with the security requirements of federal, state and local laws. Case records include written policies and procedures regarding use of medication.

24.40(2) *Performance indicators.*

a. Administration of medication.

(1) Medication administration dose schedules and standardization of abbreviations are documented.

(2) Throughout the CSRS specific methods for control and accountability of medication products are established.

(3) Prescription and over-the-counter drugs are administered or self-administered safely and properly in accordance with federal, state and local laws and regulations.

(4) Medications are prescribed by a qualified prescriber under Iowa law.

(5) Prescription drugs are not administered or self-administered without a written order signed by a qualified prescriber.

b. Staff-administered medication.

(1) Only qualified and authorized staff administers medication, and a current, accurate list of staff is maintained.

(2) Qualified prescribers instruct how medications are administered and documented. The type and amount of medication, time and date of medication administered, and the name of staff administering the medication are transcribed in the medication record.

c. Self-administered medication.

(1) Policies and procedures document which staff have completed department-approved training on self-administration of prescription medication.

(2) Self-administration of prescription and over-the-counter medications are permitted only when the medication label is clear and complete.

d. Medication storage. Medication storage policies under the care and control of the administration include:

(1) All medication is maintained in locked storage, and controlled substances are maintained in a locked box within locked storage.

(2) Medications requiring refrigeration are kept in a refrigerator separated from food and other edible items.

(3) Disinfectants and medication for external use are stored separately from internal and injectable medications.

(4) Each medication is stored in original containers and labeled with the name.

(5) All potent poisonous or caustic medications are clearly labeled; stored separately from other medication, in a specific well-illuminated cabinet, closet, or storeroom; and made accessible only to authorized staff.

(6) Medication provided is dispensed from a licensed pharmacy in the state of Iowa in accordance with the Iowa Code. It can also be provided by a qualified prescriber from a licensed pharmacy in another state according to the laws of the state.

(7) Prescription medications prescribed for one individual are not administered or allowed in the possession of another.

e. Medication labeling. All prescribed medications are clearly labeled with the full name; prescriber's name; prescription number; name and strength of the medication; dosage; directions for use; date of issue; and name, address and telephone number of the pharmacy or prescriber issuing the medication. Medications are packaged and labeled according to state and federal guidelines.

f. Monthly inspection. The staff member in charge of medication provides monthly inspection of all storage units.

g. Damaged labels. Medication containers having soiled, damaged, illegible, or makeshift labels are returned to the issuing pharmacist, pharmacy, or qualified prescriber for relabeling or disposal.

h. Unused medications. Unused prescription drugs are destroyed by staff with a witness present, when an individual leaves the crisis service without medication. A notation is documented in the record. When an individual is discharged or leaves the crisis service, medications currently being administered are sent in their original containers with the individual or with a designated person, with the approval of the qualified prescriber.

i. Medication brought by individual. If the prescribed and over-the-counter medication the individual brings to the CSRS is not used, the medication is packaged, sealed and stored. The sealed packages of medications are returned to the individual or family at the time of discharge.

j. Medication documentation.

(1) Written policies and procedures are in place for the review, approval, and implementation of ethical, safe, human and efficient behavioral intervention procedures.

(2) Written policies and procedures are in place to inform the individual and the individual's legal guardian, when appropriate, about prohibitions on the use of medication as a restraint.

(3) Documentation is required in case records on adverse drug reactions when medications are administered and self-administered.

(4) All medication orders are documented in the case records and document the name of the medication, dose, route of administration, frequency of administration, name of the qualified prescriber prescribing the medication, and name of the staff administering or dispensing the medication.

(5) Medication records are documented by authorized staff administering the medication.

k. Medication rights and responsibilities.

(1) Medication is not used as a restraint. The use of psychopharmacological medication in excess of the standard plan of care is prohibited. Using medication as a restraint includes:

1. Drugs or medications used to control behavior or restrict freedom of movement.
2. Drugs or medications used in excessive amounts or in excessive frequency.
3. Neuroleptics, anxiolytics, antihistamines, and atypical neuroleptics, or other medication used for calming, rather than for the medication's indicated treatment.

(2) Drugs or medications used for standard treatment of the individual's medical or psychiatric condition are not considered to be used as a restraint.

These rules are intended to implement Iowa Code section 331.397 and 2014 Iowa Acts, House File 2379.

[**ARC 1660C**, IAB 10/15/14, effective 12/1/14]

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[1] Effective date of definitions of "Administrator," "Division" and "Persons with mental retardation" delayed 70 days by the Administrative Rules Review Committee at its meeting held April 10, 1995.

PHARMACY BOARD[657]

[Prior to 2/10/88, see Pharmacy Examiners, Board of [620], renamed Pharmacy Examiners Board[657] under the "umbrella" of Public Health Department by 1986 Iowa Acts, ch 1245; renamed by 2007 Iowa Acts, Senate File 74]

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CHAPTER 1
PURPOSE AND ORGANIZATION

[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 9]

657—1.1(17A) Board mission. The board of pharmacy promotes, preserves, and protects the public health, safety, and welfare by fostering the provision of pharmaceutical care to all Iowans through the effective regulation of the practice of pharmacy, the operation of pharmacies, the appropriate utilization of pharmacy technicians and pharmacy support persons, the distribution of prescription drugs and devices, and the education and training of pharmacists.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—1.2(17A,147,272C) Description and organization of board. The board is comprised of five pharmacist members and two representatives of the general public, all appointed by the governor. An administrative staff headed by a board-appointed executive director assists board members.

The board's authority for regulating the practice of pharmacy and the legal distribution and dispensing of prescription drugs and devices and of precursor substances in the state of Iowa is found in Iowa Code chapters 124, 124B, 126, 147, 155A, 205, and 272C.

[**ARC 3857C**, IAB 6/20/18, effective 7/25/18]

657—1.3(17A,272C) Responsibilities. The responsibilities of the board include but are not limited to:

1. Licensing of qualified applicants for the practice of pharmacy, by examination, renewal, and reciprocity under the provisions of Iowa Code chapters 147 and 155A.
2. Administering a continuing education program to ensure continued competency of individuals licensed by the board to practice pharmacy. Authority for this function comes from Iowa Code chapter 272C.
3. Regulating the legal distribution of prescription drugs through the licensing of pharmacies and wholesalers under the authority of Iowa Code chapter 155A.
4. Regulating the legal distribution of controlled substances through the registration of authorized persons and entities engaged in the manufacture and distribution of controlled substances throughout the state under the authority of Iowa Code chapter 124.
5. Registering pharmacist-interns and administering an internship program to prepare individuals for the practice of pharmacy pursuant to the authority of Iowa Code chapter 155A.
6. Registering pharmacy technicians assisting in the technical functions of the practice of pharmacy pursuant to the authority of Iowa Code chapter 155A.
7. Performing compliance investigations and audits of all persons or entities registered pursuant to Iowa Code chapter 124 and compliance inspections and investigations of any persons or entities licensed or registered pursuant to Iowa Code chapter 155A. These investigations and audits are conducted to ensure accountability for all controlled substances and to ensure compliance with laws regulating the practice of pharmacy and the distribution of prescription drugs and devices in Iowa.
8. Regulating the legal distribution of precursor substances through the issuance of permits to vendors and recipients of precursor substances throughout the state under the authority of Iowa Code chapter 124B.
9. Instituting disciplinary actions, hearing contested cases, issuing decisions and orders, and enforcing the terms of disciplinary orders filed against licensees, registrants, or permit holders for grounds provided in Iowa Code sections 124.303, 124.304, 124B.12, 147.55, 155A.6, 155A.12, 155A.13A, 155A.15, and 155A.17, as appropriate.
10. Registering pharmacy support persons assisting in the nontechnical functions of the practice of pharmacy pursuant to the authority of Iowa Code chapter 155A.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—1.4(17A,272C) Submission of complaints and requests. Members of the general public may obtain information or submit requests or complaints relative to the practice of pharmacy, continuing education for pharmacists, the legal distribution and dispensing of prescription drugs, or any other

matters relating to the function and authority of the board. Correspondence should be submitted to the Executive Director, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. Communication may also be submitted via the board's website at www.state.ia.us/ibpe.

657—1.5(17A,21) Meetings. All meetings of the board shall be open and public, and all members of the public shall be permitted to attend any meeting unless Iowa Code section 21.5 or another provision of law authorizes a closed session. Closed session shall only be by affirmative public vote of either two-thirds of the members of the board or all of the members present at the meeting.

1.5(1) *Where held.* Meetings of the board shall be held in Des Moines, Iowa, except as designated otherwise by the chairperson.

1.5(2) *Meeting schedule and public notice.* The board shall set the dates of its meetings at the first meeting following May 1 of each fiscal year. Notices of meetings shall be routinely posted in the space set aside for that purpose in the office of the board and on the board's website at www.state.ia.us/ibpe. Members of the general public may obtain the dates, times, and locations of board meetings by submitting a request to the Executive Director, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688, or by accessing the board's website.

1.5(3) *Special meetings.* Special meetings of the board may be called by the chairperson or upon written request of four of its members.

a. The reason for calling a special meeting shall be recorded in the minutes.

b. Special meetings shall be open to the public except as otherwise provided by statute.

1.5(4) *Minutes of meetings.* The executive secretary shall keep a record of all minutes of the board, and these minutes, except as otherwise provided by statute, shall be open to the public for inspection.

1.5(5) *Quorum.* A majority of the members of the board shall constitute a quorum.

Rules 657—1.1(17A) through 657—1.5(17A,21) are intended to implement Iowa Code sections 17A.3, 21.3 through 21.5, 124.301, 147.14, 147.76, 155A.2, 272C.3, and 272C.4.

657—1.6(124,147,155A) Fee for returned check. A fee of $20 may be charged for a check returned for any reason. If a license, registration, or permit has been issued by the board office based on a check for the payment of fees and the check is later returned by the bank, the board shall request payment by certified check, cashier's check, or money order. If the fees, including the fee for a returned check, are not paid within 15 calendar days of notification of the returned check, the license, registration, or permit is no longer in effect and the status reverts to what it would have been had the license, registration, or permit not been issued. Late payment penalties will be assessed, as provided in board rules, for subsequent requests to renew or reissue the license, registration, or permit.

657—1.7(124,124B,147,155A) Overpayment of fees. "Overpayment" refers to the payment of any license, registration, permit, or service fee in excess of the required amount of the fee. Overpayment of $10 or less received by the board shall not be refunded.

These rules are intended to implement Iowa Code sections 124.301, 124B.11, 147.96, 155A.6, 155A.11, 155A.13, 155A.13A, 155A.14, and 155A.17.

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◊ Two or more ARCs

CHAPTER 3
PHARMACY TECHNICIANS
[Prior to 9/4/02, see 657—Ch 22]

657—3.1(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Board" means the Iowa board of pharmacy.

"Cashier" means a person whose duties within the pharmacy are limited to accessing finished, packaged prescription orders and processing payments for and delivering such orders to the patient or the patient's representative.

"Certified pharmacy technician" or *"certified technician"* means an individual who holds a valid current national certification and who has registered with the board as a certified pharmacy technician.

"Delivery" means the transport and conveyance of a finished, securely packaged prescription order to the patient or the patient's caregiver.

"Nationally accredited program" means a program and examination for the certification of pharmacy technicians that is accredited by the NCCA.

"NCCA" means the National Commission for Certifying Agencies.

"Pharmacy support person" means a person, other than a licensed pharmacist, a registered pharmacist-intern, or a registered pharmacy technician, who may perform nontechnical duties assigned by the pharmacist under the pharmacist's responsibility and supervision pursuant to 657—Chapter 5.

"Pharmacy technician" or *"technician"* means a person who is employed in Iowa by a licensed pharmacy under the responsibility of an Iowa-licensed pharmacist to assist in the technical functions of the practice of pharmacy, as provided in rules 657—3.22(155A) through 657—3.24(155A), and includes a certified pharmacy technician and a pharmacy technician trainee.

"Pharmacy technician certification" or *"national certification"* means a certificate issued by a national pharmacy technician certification authority accredited by the NCCA attesting that the technician has successfully completed the requirements of the certification program. The term includes evidence of renewal of the national certification.

"Pharmacy technician trainee" or *"technician trainee"* means an individual who is in training to become a pharmacy technician and who is in the process of acquiring national certification as a pharmacy technician as provided in rule 657—3.5(155A).

"Pharmacy technician training" or *"technician training"* means education or experience acquired for the purpose of qualifying for and preparing for national certification.

"Supervising pharmacist" means an Iowa-licensed pharmacist who is on duty in a licensed pharmacy in Iowa and who is responsible for the actions of a pharmacy technician or other supportive personnel.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 1785C**, IAB 12/10/14, effective 1/14/15]

657—3.2(155A) Purpose of registration. A registration program for pharmacy technicians is established for the purposes of determining the competency of a pharmacy technician or of an applicant for registration as a certified pharmacy technician or pharmacy technician trainee and for the purposes of identification, tracking, and disciplinary action for violations of federal or state pharmacy or drug laws or regulations.

[**ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 1785C**, IAB 12/10/14, effective 1/14/15]

657—3.3(155A) Registration required. Any person employed in Iowa as a pharmacy technician, except a pharmacist-intern whose pharmacist-intern registration is in good standing with the board, shall obtain and maintain during such employment a current registration as a certified pharmacy technician or pharmacy technician trainee pursuant to these rules. An individual accepting employment as a pharmacy technician in Iowa who fails to register as a certified pharmacy technician or pharmacy technician trainee as provided by these rules may be subject to disciplinary sanctions. A certified pharmacy technician accepting employment as a certified pharmacy technician in Iowa who fails to register as a certified pharmacy technician or who fails to maintain national certification may be subject to disciplinary sanctions.

3.3(1) *Licensed health care provider.* Except as provided in this rule, a licensed health care provider whose registration or license is in good standing with and not subject to current disciplinary sanctions or practice restrictions imposed by the licensee's professional licensing board and who assists in the technical functions of the practice of pharmacy shall be required to register as a certified pharmacy technician or pharmacy technician trainee pursuant to these rules.

3.3(2) *Original application required.* Any person not currently registered with the board as a pharmacy technician shall complete the appropriate application for registration within 30 days of accepting employment in an Iowa pharmacy as a pharmacy technician. Such application shall be received in the board office before the expiration of this 30-day period.

3.3(3) *Technician training.* A person who is enrolled in a college-based or American Society of Health-System Pharmacists (ASHP)-accredited technician training program shall obtain a pharmacy technician trainee registration prior to beginning on-site practical experience. A person who is employed in a pharmacy and who is receiving pharmacy technician training through work experience shall obtain a pharmacy technician trainee registration within 30 days of the commencement of pharmacy technician training.

3.3(4) *Registration number.* Each pharmacy technician registered with the board will be assigned a unique registration number.

[**ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 9407B**, IAB 3/9/11, effective 4/13/11; **ARC 1785C**, IAB 12/10/14, effective 1/14/15]

657—3.4 Reserved.

657—3.5(155A) Certification of pharmacy technicians. Except as provided in subrule 3.5(1), all pharmacy technicians shall be required to be nationally certified as provided by this rule. National certification acquired through successful completion of any NCCA-accredited pharmacy technician certification program and examination fulfills the requirement for national certification. National certification does not replace the need for licensed pharmacist control over the performance of delegated functions, nor does national certification exempt the pharmacy technician from registration pursuant to these rules. A certified pharmacy technician shall maintain the technician's national certification, in addition to the technician's Iowa registration, during any period of employment in an Iowa pharmacy as a certified pharmacy technician.

3.5(1) *Pharmacy technician trainee.* A person who is in the process of acquiring national certification as a pharmacy technician shall register with the board as a pharmacy technician trainee. The registration shall be issued for a period of one year and shall not be renewed.

3.5(2) *Certified pharmacy technician.* All applicants for a new pharmacy technician registration except as provided by subrule 3.5(1), and all applicants for renewal of a pharmacy technician registration, shall provide proof of current national pharmacy technician certification and shall complete the application for certified pharmacy technician registration.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 9407B**, IAB 3/9/11, effective 4/13/11; **ARC 1785C**, IAB 12/10/14, effective 1/14/15]

657—3.6(155A) Extension of deadline for national certification. Rescinded **ARC 1785C**, IAB 12/10/14, effective 1/14/15.

657—3.7 Reserved.

657—3.8(155A) Application form.

3.8(1) *Required information.* The application for a certified pharmacy technician registration or pharmacy technician trainee registration shall include the following:

a. Information sufficient to identify the applicant including, but not limited to, name, address, date of birth, gender, and social security number;

b. Educational background;

c. Work experience;

d. Current place or places of employment;

e. Any other information deemed necessary by the board and as provided by this rule.

3.8(2) *Declaration of current impairment or limitations.* The applicant shall declare any current use of drugs, alcohol, or other chemical substances that in any way impairs or limits the applicant's ability to perform the duties of a pharmacy technician with reasonable skill and safety.

3.8(3) *History of felony or misdemeanor crimes.* The applicant shall declare any history of being charged, convicted, found guilty of, or entering a plea of guilty or no contest to a felony or misdemeanor crime (other than minor traffic violations with fines under $100).

3.8(4) *History of disciplinary actions.* The applicant shall declare any history of disciplinary actions or practice restrictions imposed by a state health care professional or technician licensure or registration authority.

3.8(5) *Additional information.* The following additional information shall be required from an applicant for the specified registration.

a. Pharmacy technician trainee. The applicant for pharmacy technician trainee registration shall identify the source of pharmacy technician training, the anticipated date of completion of training, and the anticipated date of national certification.

b. Certified pharmacy technician. The applicant for certified pharmacy technician registration shall provide proof of current national pharmacy technician certification. The applicant shall also identify all current pharmacy employers including pharmacy name, license number, address, and average hours worked per week.

c. Licensed health care provider. In addition to the additional information required by paragraph *"a"* or *"b"* as applicable, a licensed health care provider shall provide evidence that the licensee's professional license or registration is current and in good standing and is not subject to current disciplinary sanctions or practice restrictions imposed by the licensee's professional licensing authority.

3.8(6) *Sworn signature.* The applicant shall sign the application under penalty of perjury and shall submit the application to the board with the appropriate fees pursuant to rule 657—3.10(155A).

[**ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 1785C**, IAB 12/10/14, effective 1/14/15]

657—3.9(155A) Registration term and renewal. A pharmacy technician registration shall expire as provided in this rule for the specified registration. The board shall not require continuing education for renewal of a pharmacy technician registration.

3.9(1) *Certified pharmacy technician registration.* A certified pharmacy technician registration shall expire on the second last day of the birth month following initial registration, with the exception that a new certified pharmacy technician registration issued within the two months immediately preceding the applicant's birth month shall expire on the third last day of the birth month following initial registration.

3.9(2) *Pharmacy technician trainee registration.* A registration for a pharmacy technician who is in the process of acquiring national certification (technician trainee) shall expire on the last day of the registration month 12 months following the date of registration or 12 months following the date registration was required pursuant to subrule 3.3(3).

a. National certification completed. When the registered pharmacy technician trainee completes national certification, and no later than the date of expiration of the pharmacy technician trainee registration, the pharmacy technician trainee shall complete and submit an application for certified pharmacy technician registration. A successful application shall result in issuance of a new certified pharmacy technician registration as provided in subrule 3.9(1).

b. Voluntary cancellation of registration. A registered pharmacy technician trainee who fails to complete national certification prior to expiration of the pharmacy technician trainee registration shall notify the board that the pharmacy technician trainee registration should be canceled and that the individual has ceased practice as a pharmacy technician.

c. Failure to notify the board. If a pharmacy technician trainee fails to notify the board prior to the expiration date of the pharmacy technician trainee registration regarding the individual's intentions as provided in paragraph *"a"* or *"b,"* the pharmacy technician trainee registration shall be canceled and the individual shall cease practice as a pharmacy technician.

[**ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 1785C**, IAB 12/10/14, effective 1/14/15]

657—3.10(155A) Registration fee. The following fees for initial registration and registration renewal shall apply to the specified registration applications filed within the following time frames. The appropriate fee shall be submitted with the registration application in the form of a personal check, certified check or cashier's check, or a money order payable to the Iowa Board of Pharmacy.

3.10(1) *Certified pharmacy technician registration.* The fee for obtaining an initial certified pharmacy technician registration or for biennial renewal of a certified pharmacy technician registration shall be $40 plus applicable surcharge pursuant to rule 657—30.8(155A).

3.10(2) *Technician trainee registration.* The fee for a one-year pharmacy technician trainee registration shall be $20 plus applicable surcharge pursuant to rule 657—30.8(155A).

[**ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 0504C**, IAB 12/12/12, effective 1/16/13; **ARC 1785C**, IAB 12/10/14, effective 1/14/15]

657—3.11(155A) Late applications and fees.

3.11(1) *Initial registration.* An application for initial registration that is not received within the applicable period specified in subrule 3.3(2) or 3.3(3) shall be delinquent, and the applicant shall be assessed a late payment fee. The late payment fee shall be equal to the amount of the fee for initial registration. A delinquent initial registration shall include payment of the initial registration fee, applicable surcharge pursuant to rule 657—30.8(155A), and late payment fee.

3.11(2) *Registration renewal.* A technician registration that is not renewed before its expiration date shall be delinquent, and the registrant shall not continue employment as a pharmacy technician until the registration is reactivated. An individual who continues employment as a pharmacy technician without a current registration, in addition to the pharmacy and the pharmacist in charge that allow the individual to continue practice as a pharmacy technician, may be subject to disciplinary sanctions.

a. A person who is required to renew a registration pursuant to these rules and who fails to renew the registration before the first day of the month following expiration shall pay the renewal fee, a penalty fee equal to the amount of the renewal fee, plus the applicable surcharge pursuant to rule 657—30.8(155A).

b. A person who is required to renew a registration pursuant to these rules and who fails to renew the registration before the first day of the second month following expiration shall pay the renewal fee, a penalty fee equal to the amount of the renewal fee, the applicable surcharge pursuant to rule 657—30.8(155A), plus an additional penalty fee of $10 for each additional month, not to exceed three additional months, that the registration is delinquent. The maximum combined fee payment for reactivation of a delinquent registration shall not exceed an amount equal to twice the renewal fee plus $30 plus the applicable surcharge pursuant to rule 657—30.8(155A).

c. A late payment fee shall not be assessed on an expired registration if the person was not employed as a pharmacy technician during the period following expiration of the registration.

[**ARC 0504C**, IAB 12/12/12, effective 1/16/13]

657—3.12(155A) Registration certificates. The certificate of pharmacy technician registration issued by the board to a certified pharmacy technician or pharmacy technician trainee is the property of and shall be maintained by the registered pharmacy technician. The certificate or a copy of the certificate shall be maintained in each pharmacy where the pharmacy technician works. Each pharmacy utilizing pharmacy technicians shall be responsible for verifying that all pharmacy technicians working in the pharmacy are registered, that pharmacy technician registrations remain current and active, and that a certified pharmacy technician's national certification remains current and active.

[**ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 9407B**, IAB 3/9/11, effective 4/13/11; **ARC 1785C**, IAB 12/10/14, effective 1/14/15]

657—3.13(155A) Notifications to the board. A pharmacy technician shall report to the board within ten days a change of the technician's name, address, or pharmacy employment status.

[**ARC 9009B**, IAB 8/11/10, effective 7/23/10]

657—3.14 to **3.16** Reserved.

657—3.17(155A) Training and utilization of pharmacy technicians. All licensed pharmacies located in Iowa that utilize pharmacy technicians shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy technicians appropriate to the practice of pharmacy. Pharmacy policies shall specify the frequency of review. Pharmacy technician training shall be documented and maintained by the pharmacy for the duration of employment. Policies and procedures and documentation of pharmacy technician training shall be available for inspection and copying by the board or an agent of the board.
[**ARC 1785C**, IAB 12/10/14, effective 1/14/15]

657—3.18(147,155A) Identification of pharmacy technician.

3.18(1) *Identification badge.* A pharmacy technician shall wear a visible identification badge while on duty that clearly identifies the person as a pharmacy technician and that includes at least the technician's first name.

3.18(2) *Misrepresentation prohibited.* A pharmacy technician shall not represent himself or herself in any manner as a pharmacist or pharmacist-intern. A pharmacy technician shall not represent himself or herself in any manner as a certified pharmacy technician unless the technician has attained national pharmacy technician certification.
[**ARC 9009B**, IAB 8/11/10, effective 7/23/10]

657—3.19 Reserved.

657—3.20(155A) Responsibility of supervising pharmacist. The ultimate responsibility for the actions of a pharmacy technician shall remain with the supervising pharmacist.
[**ARC 9009B**, IAB 8/11/10, effective 7/23/10]

657—3.21(155A) Delegation of functions.

3.21(1) *Technical dispensing functions.* A pharmacist may delegate technical dispensing functions to an appropriately trained and registered pharmacy technician, but only if the pharmacist is on site and available to supervise the pharmacy technician when delegated functions are performed, except as provided in 657—subrule 6.7(2) or 657—subrule 7.6(2), as appropriate, or as provided for telepharmacy in 657—Chapter 9. Except as provided for an approved tech-check-tech program pursuant to 657—Chapter 40, the pharmacist shall provide and document the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative. A pharmacy technician shall not delegate technical functions to a pharmacy support person.

3.21(2) *Nontechnical functions.* A pharmacist may delegate nontechnical functions to a pharmacy technician or a pharmacy support person only if the pharmacist is present to supervise the pharmacy technician or pharmacy support person when delegated nontechnical functions are performed, except as provided in 657—subrule 6.7(2) or 657—subrule 7.6(2), as appropriate, or as provided for telepharmacy in 657—Chapter 9.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9783B**, IAB 10/5/11, effective 11/9/11]

657—3.22(155A) Technical functions. At the discretion of the supervising pharmacist, the following technical functions, in addition to any of the functions authorized for a pharmacy support person pursuant to 657—Chapter 5, may be delegated to a pharmacy technician as specified in the following subrules.

3.22(1) *Certified pharmacy technician.* Under the supervision of a pharmacist, a certified pharmacy technician may perform technical functions delegated by the supervising pharmacist including, but not limited to, the following:

a. Perform packaging, manipulative, or repetitive tasks relating to the processing of a prescription or medication order in a licensed pharmacy.

b. Accept prescription refill authorizations communicated to a pharmacy by a prescriber or by the prescriber's agent.

c. Contact prescribers to obtain prescription refill authorizations.

d. Process pertinent patient information, including information regarding allergies and disease state.

e. Enter prescription and patient information into the pharmacy computer system.

f. Inspect drug supplies provided and controlled by an Iowa-licensed pharmacy but located or maintained outside the pharmacy department, including but not limited to drug supplies maintained in an ambulance or other emergency medical service vehicle, a long-term care facility, a hospital patient care unit, or a hospice facility.

g. Affix required prescription labels upon any container of drugs sold or dispensed pursuant to the prescription of an authorized prescriber.

h. Prepackage or label multi-dose and single-dose packages of drugs as provided in 657—Chapter 22.

i. Perform drug compounding processes as provided in 657—Chapter 20.

j. As provided in rule 657—3.24(155A), accept new prescription drug orders or medication orders communicated to the pharmacy by a prescriber or by the prescriber's agent.

3.22(2) *Pharmacy technician trainee.* Under the supervision of a pharmacist, a pharmacy technician trainee may perform only the following technical functions delegated by the supervising pharmacist:

a. Perform packaging, manipulative, or repetitive tasks relating to the processing of a prescription or medication order in a licensed pharmacy.

b. Accept prescription refill authorizations communicated to a pharmacy by a prescriber or by the prescriber's agent.

c. Contact prescribers to obtain prescription refill authorizations.

d. Process pertinent patient information, including information regarding allergies and disease state.

e. Enter prescription and patient information into the pharmacy computer system.

f. Affix required prescription labels upon any container of drugs sold or dispensed pursuant to the prescription of an authorized prescriber.

g. Prepackage or label multi-dose and single-dose packages of drugs as provided in 657—Chapter 22.

h. Under the supervision of a pharmacist who provides training and evaluates and monitors trainee competence in the compounding processes, perform drug compounding processes as provided in 657—Chapter 20.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 9502B**, IAB 5/18/11, effective 6/22/11; **ARC 1785C**, IAB 12/10/14, effective 1/14/15; **ARC 2194C**, IAB 10/14/15, effective 11/18/15]

657—3.23(155A) Tasks a pharmacy technician shall not perform. A pharmacy technician shall not be authorized to perform any of the following judgmental tasks:

1. Except for a certified pharmacy technician participating in an approved tech-check-tech program pursuant to 657—Chapter 40, provide the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order;

2. Conduct prospective drug use review or evaluate a patient's medication record for purposes identified in rule 657—8.21(155A);

3. Provide patient counseling, consultation, or patient-specific drug information, tender an offer of patient counseling on behalf of a pharmacist, or accept a refusal of patient counseling from a patient or patient's agent;

4. Make decisions that require a pharmacist's professional judgment, such as interpreting prescription drug orders or applying information;

5. Transfer a prescription drug order to another pharmacy or receive the transfer of a prescription drug order from another pharmacy;

6. Delegate technical functions to a pharmacy support person.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 9783B**, IAB 10/5/11, effective 11/9/11]

657—3.24(155A) New prescription drug orders or medication orders. At the discretion of the supervising pharmacist, a certified pharmacy technician may be allowed to accept new prescription

drug orders or medication orders communicated to the pharmacy by a prescriber or by the prescriber's agent if the certified pharmacy technician has received appropriate training pursuant to the pharmacy's policies and procedures. The supervising pharmacist shall remain responsible for ensuring the accuracy, validity, and completeness of the information received by the certified pharmacy technician. The pharmacist shall contact the prescriber to resolve any questions, inconsistencies, or other issues relating to the information received by the certified pharmacy technician that involve a pharmacist's professional judgment.
[**ARC 9009B**, IAB 8/11/10, effective 7/23/10]

657—3.25(155A) Delegation of nontechnical functions. Rescinded IAB 4/7/10, effective 6/1/10.

657—3.26 and **3.27** Reserved.

657—3.28(147,155A) Unethical conduct or practice. Violation by a pharmacy technician of any of the provisions of this rule shall constitute unethical conduct or practice and may be grounds for disciplinary action as provided in rule 657—3.30(155A).

3.28(1) *Misrepresentative deeds.* A pharmacy technician shall not make any statement tending to deceive, misrepresent, or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in pharmacy or in the operation or conduct of a pharmacy.

3.28(2) *Confidentiality.* In the absence of express written authorization from the patient or written order or direction of a court, except where the best interests of the patient require, a pharmacy technician shall not divulge or reveal to any person other than the patient or the patient's authorized representative, the prescriber or other licensed practitioner then caring for the patient, a licensed pharmacist, a person duly authorized by law to receive such information, or as otherwise provided in rule 657—8.16(124,155A), any of the following:

a. A patient's name, address, social security number, or any information that could be used to identify a patient;

b. The contents of any prescription drug order or medication order or the therapeutic effect thereof, or the nature of professional pharmaceutical services rendered to a patient;

c. The nature, extent, or degree of illness suffered by any patient; or

d. Any medical information furnished by the prescriber or the patient.

3.28(3) *Discrimination.* It is unethical to unlawfully discriminate between patients or groups of patients for reasons of religion, race, creed, color, gender, gender identity, sexual orientation, marital status, age, national origin, physical or mental disability, or disease state when providing pharmaceutical services.

3.28(4) *Unethical conduct or behavior.* A pharmacy technician shall not exhibit unethical behavior in connection with the technician's pharmacy employment. Unethical behavior shall include, but is not limited to, the following acts: verbal or physical abuse, coercion, intimidation, harassment, sexual advances, threats, degradation of character, indecent or obscene conduct, and theft.
[**ARC 9009B**, IAB 8/11/10, effective 7/23/10]

657—3.29(155A) Denial of registration. The executive director or designee may deny an application for registration as a certified pharmacy technician or pharmacy technician trainee for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs or for any violation of Iowa Code chapter 124, 124B, 126, 147, 155A, or 205 or any rule of the board.

An individual whose application for registration as a certified pharmacy technician or pharmacy technician trainee is denied pursuant to this rule may, within 30 days after issuance of the notice of denial, appeal to the board for reconsideration of the application.
[**ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 1785C**, IAB 12/10/14, effective 1/14/15; **ARC 3857C**, IAB 6/20/18, effective 7/25/18]

657—3.30(155A) Discipline of pharmacy technicians.

3.30(1) *Violations.* The board may impose discipline for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs, or for any violation of Iowa Code chapter 124, 124B, 126, 147, 155A, or 205 or any rule of the board.

3.30(2) *Sanctions.* The board may impose the following disciplinary sanctions:

a. Revocation of a certified pharmacy technician or pharmacy technician trainee registration.

b. Suspension of a certified pharmacy technician or pharmacy technician trainee registration until further order of the board or for a specified period.

c. Nonrenewal of a certified pharmacy technician registration.

d. Prohibition, permanently, until further order of the board, or for a specified period, from engaging in specified procedures, methods, or acts.

e. Probation.

f. The ordering of a physical or mental examination.

g. The imposition of civil penalties not to exceed $25,000.

h. Issuance of a citation and warning.

i. Such other sanctions allowed by law as may be appropriate.

[**ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 1785C**, IAB 12/10/14, effective 1/14/15; **ARC 3857C**, IAB 6/20/18, effective 7/25/18]

These rules are intended to implement Iowa Code sections 147.72, 147.107, 155A.6A, 155A.23, 155A.33, and 155A.39.

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CHAPTER 4
PHARMACIST-INTERNS
[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 3]

657—4.1(155A) Definitions.

"Board" means the Iowa board of pharmacy.

"Pharmacist-intern" or *"intern"* means a person enrolled in a college of pharmacy or actively pursuing a pharmacy degree, or as otherwise provided by the board, who is registered with the board for the purpose of obtaining instruction in the practice of pharmacy from a preceptor pursuant to Iowa Code section 155A.6. "Pharmacist-intern" includes a graduate of an approved college of pharmacy, or a foreign graduate who has established educational equivalency pursuant to the requirements of rule 657—4.7(155A), who is registered with the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist in Iowa. "Pharmacist-intern" may include an individual participating in a residency or fellowship program in Iowa, whether or not the individual is licensed as a pharmacist in another state.

"Pharmacist preceptor" or *"preceptor"* means a pharmacist licensed to practice pharmacy whose license is current and in good standing. Preceptors shall meet the conditions and requirements of rule 657—4.9(155A). No pharmacist shall serve as a preceptor while the pharmacist's license to practice pharmacy is the subject of disciplinary sanction by a pharmacist licensing authority.

[**ARC 9784B**, IAB 10/5/11, effective 11/9/11; **ARC 1406C**, IAB 4/2/14, effective 5/7/14]

657—4.2(155A) Goal and objectives of internship.

4.2(1) *Goal.* The goal of internship is for the pharmacist-intern, over a period of time, to attain and build upon the knowledge, skills, responsibilities, and ability to safely, efficiently, and effectively practice pharmacy under the laws and rules of the state of Iowa.

4.2(2) *Objectives.* The objectives of internship are as follows:

a. Managing drug therapy to optimize patient outcomes. The pharmacist-intern shall evaluate the patient and patient information to determine the presence of a disease or medical condition, to determine the need for treatment or referral, and to identify patient-specific factors that affect health, pharmacotherapy, or disease management; ensure the appropriateness of the patient's specific pharmacotherapeutic agents, dosing regimens, dosage forms, routes of administration, and delivery systems; and monitor the patient and patient information and manage the drug regimen to promote health and ensure safe and effective pharmacotherapy.

b. Ensuring the safe and accurate preparation and dispensing of medications. The pharmacist-intern shall perform calculations required to compound, dispense, and administer medication; select and dispense medications; and prepare and compound extemporaneous preparations and sterile products.

c. Providing drug information and promoting public health. The pharmacist-intern shall access, evaluate, and apply information to promote optimal health care; educate patients and health care professionals regarding prescription medications, nonprescription medications, and medical devices; and educate patients and the public regarding wellness, disease states, and medical conditions.

d. Adhering to professional and ethical standards. The pharmacist-intern shall comply with professional, legal, moral, and ethical standards relating to the practice of pharmacy and the operation of the pharmacy.

e. Understanding the management of pharmacy operations. The pharmacist-intern shall develop a general understanding of the business procedures of a pharmacy and develop knowledge concerning the employment and supervision of pharmacy employees.

657—4.3(155A) 1500-hour requirements. Internship credit may be obtained only after internship registration with the board and commencement of the first professional year in a college of pharmacy. Internship shall consist of a minimum of 1500 hours, all of which may be a college-based clinical program approved or accepted by the board. Programs shall be structured to provide experience in community, institutional, and clinical pharmacy practices. A pharmacist-intern may acquire additional

hours under the supervision of one or more preceptors in a traditional licensed general or hospital pharmacy, at a rate of no more than 48 hours per week, where the goal and objectives of internship in rule 657—4.2(155A) apply. Credit toward any additional hours will be allowed, at a rate not to exceed 10 hours per week, for an internship served concurrent with academic training and outside a college-based clinical program. "Concurrent time" means internship experience acquired while the person is a full-time student carrying, in a given school term, at least 75 percent of the average number of credit hours per term needed to graduate and receive an entry-level degree in pharmacy. Recognized academic holiday periods, such as spring break and winter break, shall not be considered "concurrent time." The competencies in subrule 4.2(2) and the concurrent time limitations of this rule shall not apply to college-based clinical programs.
[**ARC 1406C**, IAB 4/2/14, effective 5/7/14]

657—4.4(155A) Iowa colleges of pharmacy clinical internship programs. The board shall periodically review the clinical component of internship programs of the colleges of pharmacy located in Iowa. The board reserves the right to set conditions relating to the approval of such programs.

657—4.5(155A) Out-of-state internship programs. Candidates enrolled in out-of-state colleges of pharmacy who complete the internship requirements of that state shall be deemed to have satisfied Iowa's internship requirements. Candidates shall submit documentation from the out-of-state internship program certifying completion of that state's requirements. Candidates enrolled in colleges of pharmacy located in states with no formal internship training program shall submit documentation from that state's board of pharmacy or college of pharmacy certifying that the candidate has completed all prelicensure training requirements.

657—4.6(155A) Registration, reporting, and authorized functions. Every person shall register with the board before beginning the person's internship experience, whether or not for the purpose of fulfilling the requirements of rule 657—4.3(155A). Registration is required of all students enrolled in Iowa colleges of pharmacy upon commencement of the first professional year in the college of pharmacy. Colleges of pharmacy located in Iowa shall annually certify to the board the names of students who are enrolled in the first professional year in the college of pharmacy. Colleges of pharmacy located in Iowa shall, within two weeks of any change, certify to the board the names of students who have withdrawn from the college of pharmacy.

4.6(1) *Application for registration—required information.* Application for registration as a pharmacist-intern shall be on forms provided by the board, and all requested information shall be provided on or with such application. The application shall require that the applicant provide, at a minimum, the following: name; address; telephone number; date of birth; social security number or individual tax identification number (ITIN); and name and location of college of pharmacy and anticipated month and year of graduation. The college of pharmacy shall certify the applicant's eligibility to practice as a pharmacist-intern.

4.6(2) *Supervision and authorized functions.* A licensed pharmacist shall be on duty in the pharmacy and shall be responsible for the actions of a pharmacist-intern during all periods of internship training. At the discretion of the supervising pharmacist, the following judgmental functions, usually restricted to a pharmacist, may be delegated to pharmacist-interns registered by the board:

a. Verification of the accuracy, validity, and appropriateness of the filled prescription or medication order;

b. Review and assessment of patient records for purposes identified in rule 657—8.21(155A);

c. Patient counseling;

d. Administration of vaccines pursuant to rule 657—39.10(155A).

4.6(3) *Term of registration.* Registration shall remain in effect as long as the board is satisfied that the intern is pursuing a degree in pharmacy in good faith and with reasonable diligence. A pharmacist-intern may request that the intern's registration be extended beyond the automatic termination of the registration pursuant to the procedures and requirements of 657—Chapter 34. Except as provided by the definition

of pharmacist-intern in rule 657—4.1(155A), registration shall automatically terminate upon the earliest of any of the following:

a. Licensure to practice pharmacy in any state;

b. Lapse in the pursuit of a degree in pharmacy; or

c. One year following graduation from the college of pharmacy.

4.6(4) *Identification, reports, and notifications.* Credit for internship time will not be granted unless registration and other required records or affidavits are completed.

a. The pharmacist-intern shall be so designated in all relationships with the public and health professionals. While on duty in the pharmacy, the intern shall wear visible to the public a name badge including the designation "pharmacist-intern" or "pharmacy student."

b. Registered interns shall notify the board office within ten days of a change of name or address.

c. Notarized affidavits of experience in non-college-sponsored programs shall be filed with the board office after the successful completion of the internship. These affidavits shall certify only the number of hours and dates of training obtained outside a college-based clinical program as provided in rule 657—4.3(155A). An individual registered as a pharmacist-intern while participating in an Iowa residency or fellowship program shall not be required to file affidavits of experience.

4.6(5) *No credit prior to registration.* Credit will not be given for internship experience obtained prior to the individual's registration as a pharmacist-intern. Credit for Iowa college-based clinical programs will not be granted unless registration is issued before the student begins the program.

4.6(6) *Nontraditional internship.* Internship training at any site which is not licensed as a general or hospital pharmacy is considered nontraditional internship.

a. Application. Prior to beginning a period of nontraditional internship, the intern shall submit a written application, on forms provided by the board, for approval of the objectives of the nontraditional internship. The application shall identify objectives consistent with the unique learning experiences of the intern and consistent with the goal and objectives of internship in rule 657—4.2(155A).

b. Preceptor. A preceptor supervising a pharmacist-intern in a nontraditional internship shall be a currently licensed pharmacist in the state where the internship is served, and the requirements of rule 657—4.9(155A) shall apply to all preceptors.

c. Certification, not credit. Hours obtained in nontraditional internship shall not be credited toward the total 1500 hours required pursuant to rule 657—4.3(155A) prior to licensure to practice pharmacy in Iowa. The board may, however, certify hours obtained in one or more approved nontraditional internships in recognition of the pharmacist-intern's training outside the scope of traditional pharmacy practice. Certification shall not be granted for experience obtained in a nontraditional internship unless the board, prior to the intern's beginning the period of internship, approved the objectives of the internship.

[**ARC 9784B**, IAB 10/5/11, effective 11/9/11; **ARC 1406C**, IAB 4/2/14, effective 5/7/14; **ARC 1786C**, IAB 12/10/14, effective 1/14/15; **ARC 2405C**, IAB 2/17/16, effective 3/23/16; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—4.7(155A) Foreign pharmacy graduates. Foreign pharmacy graduates who are candidates for licensure in Iowa will be required to obtain a minimum of 1500 hours of internship in a licensed pharmacy or other board-approved location.

4.7(1) *Registration.* Candidates shall register with the board as provided in rule 657—4.6(155A). Internship credit will not be granted until the candidate has been issued an intern registration. Applications for registration shall be accompanied by certification from the Foreign Pharmacy Graduate Examination Committee (FPGEC) as provided in 657—subrule 2.10(1).

4.7(2) *Certification of hours.* Following completion of any period of internship, internship hours shall be certified to the board by submission of notarized affidavits of experience as provided in paragraph 4.6(4)*"c."*

4.7(3) *Credit for foreign pharmacy practice.* The board may grant credit to a foreign pharmacy graduate, based on the candidate's experience in the practice of pharmacy, for all or any portion of the required 1500 hours of internship training. The candidate shall provide detailed information regarding the candidate's experience in the practice of pharmacy. The board shall determine, on a case-by-case

basis, whether and to what extent the candidate's experience meets the goals and objectives established in rule 657—4.2(155A).
[**ARC 1406C**, IAB 4/2/14, effective 5/7/14]

657—4.8(155A) Fees. The fee for registration as a pharmacist-intern is $30, plus applicable surcharge pursuant to 657—30.8(155A), which shall be payable with the application.

657—4.9(155A) Preceptor requirements.

4.9(1) *Licensed pharmacist.* A preceptor shall be a licensed pharmacist in good standing in the state where the internship is to be served pursuant to the definition of pharmacist preceptor in rule 657—4.1(155A).

4.9(2) *Affidavits.* A preceptor shall be responsible for completing the affidavit certifying the number of hours and the dates of each internship training period under the supervision of the preceptor for any period of internship completed outside a college-based clinical program.

4.9(3) *Number of interns.* A preceptor may supervise no more than two pharmacist-interns concurrently.

4.9(4) *Responsibility.* A preceptor shall be responsible for all functions performed by a pharmacist-intern.
[**ARC 1406C**, IAB 4/2/14, effective 5/7/14]

657—4.10(155A) Denial of pharmacist-intern registration. The board may deny an application for registration as a pharmacist-intern for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs, or for any violation of Iowa Code chapter 124, 124B, 126, 147, 155A or 205, or any rule of the board.
[**ARC 3857C**, IAB 6/20/18, effective 7/25/18]

657—4.11(155A) Discipline of pharmacist-interns.

4.11(1) *Grounds for discipline.* The board may impose discipline for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs or for any violation of Iowa Code chapter 124, 124B, 126, 147, 155A, or 205, or any rule of the board.

4.11(2) *Sanctions.* The board may impose the following disciplinary sanctions:

a. Revocation of a pharmacist-intern registration.

b. Suspension of a pharmacist-intern registration until further order of the board or for a specified period.

c. Prohibit permanently, until further order of the board, or for a specified period, the engaging in specified procedures, methods, or acts.

d. Such other sanctions allowed by law as may be appropriate.
[**ARC 3857C**, IAB 6/20/18, effective 7/25/18]

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CHAPTER 5
PHARMACY SUPPORT PERSONS

657—5.1(155A) Definitions. For purposes of this chapter, the following definitions shall apply:

"Board" means the Iowa board of pharmacy.

"Delivery" means the transport and conveyance of a finished, securely packaged prescription order to the patient or the patient's agent.

"Direct access" means physical access, without direct supervision by a pharmacist, to opened, unpackaged, or unsecured stock containers or prescription vials containing prescription drugs.

"Pharmacy clerk" means a person whose duties within the pharmacy department include accessing filled prescription orders and processing payments for and delivering such orders to the patient or the patient's agent under the supervision of a pharmacist.

"Pharmacy support person" means a person, other than a licensed pharmacist, a registered pharmacist-intern, or a registered pharmacy technician, who may perform nontechnical duties assigned by a supervising pharmacist under the pharmacist's responsibility and supervision.

"Pharmacy technician" or *"technician"* means a person who is employed in Iowa by a licensed pharmacy under the responsibility of an Iowa-licensed pharmacist to assist in the technical functions of the practice of pharmacy, and who is registered pursuant to 657—Chapter 3, and includes a certified pharmacy technician, a pharmacy technician trainee, and an uncertified pharmacy technician.

"Secure package" means the prescription order is enclosed in tamper-evident packaging. An IV bag is considered tamper-evident packaging.

"Supervising pharmacist" means an Iowa-licensed pharmacist who is on duty in an Iowa-licensed pharmacy and who is responsible for assigning and supervising the duties performed by a pharmacy support person.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9009B**, IAB 8/11/10, effective 7/23/10]

657—5.2(155A) Purpose of registration. A registration program for pharmacy support persons is established for the purposes of identification, tracking, and disciplinary action. The registration shall not include any determination of the competency of the registered individual. The use of pharmacy support persons to assist the pharmacist with nontechnical duties associated with the practice of pharmacy enables the pharmacist to provide pharmaceutical care to the patient.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.3 Reserved.

657—5.4(155A) Registration required.

5.4(1) *Effective date.* Beginning June 1, 2010, a pharmacy support person shall register with the board pursuant to the requirements of this chapter.

5.4(2) *Registration number.* Each pharmacy support person registered with the board will be assigned a unique registration number.

5.4(3) *Original application required.* Any person required to register and not previously registered with the board as a pharmacy support person shall complete an application for registration within 30 days of accepting employment in an Iowa pharmacy as a pharmacy support person. Such application shall be received in the board office before the expiration of this 30-day period.

5.4(4) *Employment terminated.* A registered pharmacy support person who discontinues employment as a pharmacy support person shall not be required to maintain a registration and shall request cancellation of the registration as provided in rule 657—5.14(155A).

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.5(155A) Exempt from registration. Unless a person has direct access to prescription drugs, the following shall be exempt from registration as a pharmacy support person:

1. Delivery person.
2. Billing clerk, including a person who processes claims for third-party payments.

3. Data processing support, maintenance, or programming personnel.

4. Facility maintenance personnel including but not necessarily limited to cleaning, sanitation, structural, and mechanical maintenance personnel. Facility maintenance personnel deemed exempt from registration shall be directly supervised by a pharmacist or a certified pharmacy technician who is responsible for the maintenance person's activities within the pharmacy department to ensure medication security and patient privacy.

5. Any person not directly employed by or under contract to the pharmacy, and not under the direct supervision of a pharmacist, who provides data processing, billing, maintenance, or administrative support functions outside the pharmacy department.

6. A registered pharmacist-intern or a registered pharmacy technician.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.6 Reserved.

657—5.7(155A) Registration application form.

5.7(1) *Required information.* The application form for a pharmacy support person registration shall require the following:

a. Information sufficient to identify the applicant including, but not limited to, name, address, date of birth, gender, and social security number;

b. Educational background;

c. Work experience;

d. Current place or places of employment;

e. Any other information deemed necessary by the board.

5.7(2) *Declaration of current impairment or limitations.* The applicant shall declare any current use of drugs, alcohol, or other chemical substances that in any way impairs or limits the applicant's ability to perform the duties of a pharmacy support person with reasonable skill and safety.

5.7(3) *History of felony or misdemeanor crimes.* The applicant shall declare any history of being charged, convicted, found guilty of, or entering a plea of guilty or no contest to a felony or misdemeanor crime (other than minor traffic violations with fines under $100).

5.7(4) *History of disciplinary actions.* The applicant shall declare any history of disciplinary actions or practice restrictions imposed by a state health care professional, licensure, or registration authority.

5.7(5) *Sworn signature.* The applicant shall sign the application under penalty of perjury and shall submit the application to the board with the appropriate fees pursuant to rules 657—5.9(155A) and 657—5.11(155A).

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.8 Reserved.

657—5.9(155A) Registration fee.

5.9(1) *Initial fee.* The fee for obtaining an initial registration shall be $25.

5.9(2) *Renewal fee.* The renewal fee for obtaining a biennial registration shall be $25.

5.9(3) *Timeliness.* Fees shall be paid at the time the new application or the renewal application is submitted for filing.

5.9(4) *Form of payment.* Fee payment shall be in the form of a personal check, certified or cashier's check, or money order payable to Iowa Board of Pharmacy.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 0504C**, IAB 12/12/12, effective 1/16/13]

657—5.10(155A) Registration renewal. A pharmacy support person registration shall expire on the second last day of the birth month following initial registration. Registration shall not require continuing education for renewal.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.11(155A) Late application.

5.11(1) *Fee.* A person required to register or to renew the person's registration who files a late application shall pay an additional $25 late payment fee.

5.11(2) *Timeliness of initial application.* An application for initial registration shall be assessed a late payment fee if not received within the applicable period specified in rule 657—5.4(155A).

5.11(3) *Timeliness of renewal application.* An application for registration renewal shall be assessed a late payment fee if not received by the expiration date of the registration. A late payment fee shall not be assessed on an expired registration if the person was not employed as a pharmacy support person during the period following expiration of the registration.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 0504C**, IAB 12/12/12, effective 1/16/13]

657—5.12 Reserved.

657—5.13(155A) Registration certificates. The original registration certificate issued by the board to a pharmacy support person shall be maintained by the pharmacy support person. Verification of current registration shall be maintained in each pharmacy where the pharmacy support person is employed in that capacity and shall be available for inspection by the board.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.14(155A) Notifications to the board. A pharmacy support person shall report to the board within ten days a change of name, address, place of employment, or employment status.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.15(155A) Identification of pharmacy support person.

5.15(1) *Name badge.* A pharmacy support person shall wear a name badge or other form of identification while on duty which clearly identifies the person as a pharmacy support person.

5.15(2) *Misrepresentation prohibited.* A pharmacy support person shall not, in any manner, represent himself or herself as a pharmacist, a pharmacist-intern, or a pharmacy technician.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.16 Reserved.

657—5.17(155A) Tasks a pharmacy support person shall not perform. A pharmacy support person shall not perform any of the following judgmental or technical functions. Performance of any of these tasks by a pharmacy support person shall constitute the practice of pharmacy without a license in violation of Iowa Code section 155A.7. A pharmacy support person shall not:

1. Provide the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order.
2. Conduct prospective drug use review or evaluate a patient's medication record for purposes identified in rule 657—8.21(155A).
3. Provide patient counseling, consultation, or patient-specific drug information; make an offer of patient counseling on behalf of the pharmacist; or accept a refusal of patient counseling from a patient or patient's agent.
4. Make decisions that require a pharmacist's professional judgment, such as interpreting or applying information.
5. Accept by oral communication any new or refill prescription authorizations communicated to a pharmacy by a prescriber or by the prescriber's office or contact a prescriber to obtain prescription refill authorizations.
6. Provide a prescription or drug to a patient without a pharmacist's verification as to the accuracy of the dispensed medication and without the physical presence of a pharmacist.
7. Package, pour, or place in a container for dispensing, sale, distribution, transfer, vending, or barter any drug which, under federal or state laws, may be sold or dispensed only pursuant to the prescription of a practitioner authorized to prescribe drugs. This prohibited task includes the addition of water or other liquid for reconstitution of oral antibiotic liquids. A pharmacy support person may place

a prescription container into a bag or sack for delivery to the patient as part of the sales transaction after the accuracy of the prescription has been verified by the pharmacist.

8. Affix required prescription labels upon any container of drugs sold or dispensed pursuant to the prescription of an authorized prescriber.

9. Process or enter pertinent patient or prescription information, including entry of that information into the pharmacy computer system, except as provided in rule 657—5.18(155A).

10. Prepackage or label multidose and single-dose packages of drugs, including dose picks for unit dose cart fills for hospital or long-term care facility patients.

11. Check or inspect drug supplies provided and controlled by an Iowa-licensed pharmacy but located or maintained outside the pharmacy department, including but not limited to drug supplies maintained in an ambulance or other emergency medical service vehicle, a long-term care facility, a hospital nursing unit, or a hospice facility.

12. Reconstitute prefabricated noninjectable medication, prepare parenteral products, or compound sterile or nonsterile drug products.

13. Communicate, transmit, or receive patient or prescription information to or from the pharmacy for the purpose of transferring a patient's prescription between pharmacies.

14. Assist with or witness the destruction or wastage of controlled substances pursuant to 657—subrule 10.22(2).

15. Perform any of the duties identified in 657—Chapter 3 as technical functions that may be delegated to a pharmacy technician.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9785B**, IAB 10/5/11, effective 11/9/11; **ARC 3637C**, IAB 2/14/18, effective 3/21/18]

657—5.18(155A) Nontechnical pharmacy support tasks. An appropriately trained and registered pharmacy support person may perform any of the following nontechnical functions that have been delegated to the pharmacy support person by the supervising pharmacist:

1. Perform the duties of a pharmacy clerk. The duties of a pharmacy clerk may include placing a prescription container into a bag or sack for delivery to the patient as part of the sales transaction after the accuracy of the prescription has been verified by the pharmacist.

2. Process wholesale drug orders, including the submission of orders, the receipt and processing of drug deliveries from drug wholesalers, reconciling products received with packing slips or invoices, and affixing appropriate inventory or price stickers to drug stock bottles or containers.

3. Perform routine clerical duties, such as filing processed, hard-copy prescriptions and other pharmacy records.

4. Update or change patient demographic information, excluding allergies and disease state information, in the pharmacy computer system or patient profile.

5. Receive from a patient the patient's request for a prescription refill, excluding the processing of the refill request.

6. Perform pharmacy drug inventory control duties, including checking pharmacy stock shelves for outdated drugs and assisting with annual inventory counts.

7. Deliver drugs to patient care areas, long-term care facilities, patient residences, or patient employment locations, excluding the restocking of automated medication distribution system components.

8. Perform any routine clerical or pharmacy support function not prohibited in rule 657—5.17(155A).

9. In nuclear pharmacy practice, perform nonjudgmental tasks under the direct supervision of a nuclear pharmacist pursuant to 657—Chapter 16.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9785B**, IAB 10/5/11, effective 11/9/11]

657—5.19 Reserved.

657—5.20(155A) Training and utilization of pharmacy support persons. All Iowa-licensed pharmacies utilizing pharmacy support persons shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy support persons. Pharmacy

policies shall specify the frequency of review. Pharmacy support person training shall be documented and maintained by the pharmacy for the duration of employment. Such policies and procedures and documentation of pharmacy support person training shall be available for inspection by the board or an agent of the board.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.21(155A) Responsibility of supervising pharmacist. The ultimate responsibility for the actions of a pharmacy support person working under a supervising pharmacist shall remain with the supervising pharmacist.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.22(155A) Delegation of nontechnical functions. A pharmacist may delegate nontechnical functions to an appropriately trained and registered pharmacy support person, but only if the pharmacist is present to supervise the pharmacy support person when delegated functions are performed, except as provided in 657—subrule 6.7(2) or 657—subrule 7.6(2), as appropriate.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.23 Reserved.

657—5.24(155A) Denial of registration. The board may deny an application for registration as a pharmacy support person for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs or for any violation of Iowa Code chapter 124, 124B, 126, 147, 155A, or 205 or any rule of the board.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 3857C**, IAB 6/20/18, effective 7/25/18]

657—5.25(147,155A) Unethical conduct or practice. Violation by a pharmacy support person of any of the provisions of this rule shall constitute unethical conduct or practice and may be grounds for disciplinary action as provided in rule 657—5.26(155A).

5.25(1) *Misrepresentative deeds.* A pharmacy support person shall not make any statement tending to deceive, misrepresent or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in pharmacy or in the operation or conduct of a pharmacy.

5.25(2) *Confidentiality.* In the absence of express consent from the patient or order or direction of a court, except where the best interests of the patient require, a pharmacy support person shall not divulge or reveal to any person other than the patient or the patient's authorized representative, the prescriber or other licensed practitioner then caring for the patient, a licensed pharmacist, or a person duly authorized by law to receive such information the contents of any prescription or the therapeutic effect thereof or the nature of professional pharmaceutical services rendered to a patient; the nature, extent, or degree of illness suffered by any patient; or any medical information furnished by the prescriber.

5.25(3) *Discrimination.* It is unethical for a pharmacy support person to unlawfully discriminate between patients or groups of patients for reasons of religion, race, creed, color, sex, sexual orientation, gender identity, age, national origin, or disease state when providing pharmaceutical services.

5.25(4) *Unethical conduct or behavior.* A pharmacy support person shall not exhibit unethical behavior in connection with the pharmacy support person's pharmacy employment. Unethical behavior shall include, but is not limited to, the following acts: verbal abuse, coercion, intimidation, harassment, sexual advances, threats, degradation of character, indecent or obscene conduct, and theft.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.26(155A) Discipline of pharmacy support persons.

5.26(1) *Violations.* The board may impose discipline for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs or for any violation of Iowa Code chapter 124, 124B, 126, 147, 155A, or 205 or any rule of the board.

5.26(2) *Sanctions.* The board may impose the following disciplinary sanctions:

a. Revocation of a pharmacy support person registration.

b. Suspension of a pharmacy support person registration until further order of the board or for a specified period.

c. Nonrenewal of a pharmacy support person registration.

d. Prohibition, permanently, until further order of the board, or for a specified period, from engaging in specified procedures, methods, or acts.

e. Probation.

f. Imposition of civil penalties not to exceed $25,000.

g. Issuance of citation and warning.

h. Such other sanctions allowed by law as may be appropriate.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 3857C**, IAB 6/20/18, effective 7/25/18]

These rules are intended to implement Iowa Code sections 147.55, 155A.3, 155A.18 and 155A.23 and 2009 Iowa Code Supplement section 155A.6B.

[Filed ARC 8673B (Notice ARC 8380B, IAB 12/16/09), IAB 4/7/10, effective 6/1/10]
[Filed Emergency ARC 9009B, IAB 8/11/10, effective 7/23/10]
[Filed ARC 9785B (Notice ARC 9556B, IAB 6/15/11), IAB 10/5/11, effective 11/9/11]
[Filed ARC 0504C (Notice ARC 0351C, IAB 10/3/12), IAB 12/12/12, effective 1/16/13]
[Filed ARC 3637C (Notice ARC 3370C, IAB 10/11/17), IAB 2/14/18, effective 3/21/18]
[Filed ARC 3857C (Notice ARC 3506C, IAB 12/20/17), IAB 6/20/18, effective 7/25/18]

CHAPTER 8
UNIVERSAL PRACTICE STANDARDS
[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 6]

657—8.1(155A) Purpose and scope. The purpose of this chapter is to establish the minimum standards of pharmacy practice for the activities identified in this chapter. The requirements of these rules shall apply to all Iowa-licensed pharmacists, other registered pharmacy personnel, and all pharmacies, including owners, providing the services addressed in this chapter to patients in Iowa. These rules are in addition to rules of the board relating to specific types of pharmacy licenses issued by the board unless otherwise indicated by rule.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.2(155A) Definitions. For the purpose of this chapter, the following definitions shall apply:

"Board" means the Iowa board of pharmacy.

"Confidential information" means information accessed or maintained by the pharmacy in the patient's or the pharmacy's records which contains personally identifiable information that could be used to identify the patient. "Confidential information" includes but is not limited to patient name, address, telephone number, and social security number; prescriber name and address; and prescription and drug or device information such as therapeutic effect, diagnosis, allergies, disease state, pharmaceutical services rendered, medical information, and drug interactions.

"DEA" means the United States Department of Justice, Drug Enforcement Administration.

"Pharmacy support person" or *"PSP"* means a person, other than a member of the professional pharmacy staff, registered with the board who may perform nontechnical duties assigned by a supervising pharmacist under the pharmacist's responsibility and supervision.

"Professional pharmacy staff" shall mean the professional employees of the pharmacy, including pharmacists, pharmacy technicians, and pharmacist-interns.

This rule is intended to implement Iowa Code chapter 155A.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.3(155A) Responsible parties.

8.3(1) *Pharmacist in charge.* One professionally competent, legally qualified pharmacist in charge in each pharmacy shall work cooperatively with the pharmacy, by and through its owner or license holder, and with all staff pharmacists to ensure the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy. A part-time pharmacist in charge has the same obligations and responsibilities as a full-time pharmacist in charge.

8.3(2) *Pharmacy.* Each pharmacy, by and through its owner or license holder, shall work cooperatively with the pharmacist in charge and with all staff pharmacists to ensure the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy. The pharmacy, by and through its owner or license holder, shall be responsible for employing a professionally competent, legally qualified pharmacist in charge. The pharmacy, by and through its owner or license holder, may be held responsible for unethical conduct or practices of any of the pharmacy staff.

8.3(3) *Pharmacy and pharmacist in charge.* The pharmacist in charge and the pharmacy, by and through its owner or license holder, shall share responsibility for, at a minimum, the following:

a. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy.

b. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy.

c. Ensuring that there is adequate space within the prescription department or a locked room not accessible to the public for the storage of prescription drugs, including controlled substances, devices, and pharmacy records, and to support the operations of the pharmacy.

d. Ensuring that the license, registration, or certification of each professional pharmacy staff member and the registration of each pharmacy support person are maintained in current and active status.

8.3(4) *Pharmacist in charge and staff pharmacists.* The pharmacist in charge and staff pharmacists shall share responsibility for, at a minimum, the following:

a. Ensuring that a pharmacist performs prospective drug use review as specified in rule 657—8.21(155A).

b. Ensuring that a pharmacist or pharmacist-intern provides patient counseling as specified in rule 657—6.14(155A).

c. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.

d. Delivering drugs to the patient or the patient's agent.

e. Ensuring that patient medication records are maintained as specified in rule 657—6.13(155A).

f. Training and supervising pharmacist-interns, pharmacy technicians, pharmacy support persons, and other pharmacy employees.

g. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.

h. Distributing and disposing of drugs from the pharmacy.

i. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations.

j. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.

8.3(5) *Pharmacy, pharmacist in charge, and staff pharmacists.* The pharmacy, by and through its owner or license holder, the pharmacist in charge, and all staff pharmacists shall share responsibility for, at a minimum, the following:

a. Establishing and periodically reviewing (by the pharmacy and the pharmacist in charge), implementing (by the pharmacist in charge), and complying (by the pharmacist in charge and staff pharmacists) with policies and procedures for all operations of the pharmacy. The policies and procedures shall identify the frequency of review.

b. Establishing and maintaining effective controls against the theft or diversion of prescription drugs, including controlled substances, and records for such drugs.

c. Establishing (by the pharmacy and the pharmacist in charge), implementing (by the pharmacist in charge), and utilizing (by the pharmacist in charge and staff pharmacists) an ongoing, systematic program of continuous quality improvement for achieving performance enhancement and ensuring the quality of pharmaceutical services.

8.3(6) *Practice functions.* The pharmacist is responsible for all functions performed in the practice of pharmacy. The pharmacist maintains responsibility for any and all delegated functions including functions delegated to pharmacist-interns, pharmacy technicians, and pharmacy support persons.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 1576C**, IAB 8/20/14, effective 9/24/14; **ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.4(155A) Pharmacist identification and staff logs.

8.4(1) *Display of pharmacist license.* During any period a pharmacist is working in a pharmacy, each pharmacist shall display, in a position visible to the public, an original license to practice pharmacy in Iowa. A current license renewal certificate, which may be a photocopy of an original renewal certificate, shall be displayed with the original license.

8.4(2) *Registration maintained of pharmacy personnel.* Each pharmacist-intern, pharmacy technician, and pharmacy support person shall maintain current registration with the board. The registration certificate or a copy of the registration certificate shall be readily retrievable upon request of the board or its authorized agent.

8.4(3) *Identification codes.* A permanent log of the initials or identification code identifying by name each pharmacist, pharmacist-intern, pharmacy technician, and pharmacy support person shall be maintained for a minimum of two years and shall be available for inspection and copying by the board or its representative. The initials or identification code shall be unique to the individual to ensure that each pharmacist, pharmacist-intern, pharmacy technician, and pharmacy support person can be identified.

8.4(4) *Temporary or intermittent pharmacy staff.* The pharmacy shall maintain a log of all pharmacists, pharmacist-interns, pharmacy technicians, and pharmacy support persons who have worked at that pharmacy and who are not regularly staffed at that pharmacy. Such log shall include the dates and shifts worked by each pharmacist, pharmacist-intern, pharmacy technician, and pharmacy support person and shall be available for inspection and copying by the board or its representative for a minimum of two years following the date of the entry.

8.4(5) *Identification.* While on duty, pharmacy personnel shall wear visible identification that clearly identifies the person by licensed or registered title and includes at least the person's first name.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9409B**, IAB 3/9/11, effective 4/13/11; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.5(155A) Environment and equipment requirements. There shall be adequate space, equipment, and supplies for the professional and administrative functions of the pharmacy pursuant to rule 657—8.3(155A). Space and equipment in an amount and type to provide secure, environmentally controlled storage of drugs shall be available.

8.5(1) *Refrigeration.* The pharmacy shall maintain one or more refrigeration units, unless the pharmacy does not stock refrigerated items. The pharmacy shall document verification that the temperature of the refrigerator is maintained within a range compatible with the proper storage of drugs requiring refrigeration. If the temperature is manually or visually verified, a record of minimum daily verification shall be maintained.

8.5(2) *Sink.* The pharmacy shall have a sink with hot and cold running water located within the pharmacy department and available to all pharmacy personnel; the sink shall be maintained in a sanitary condition.

8.5(3) *Secure barrier.* A pharmacy department shall be closed and secured in the absence of the pharmacist except as provided in rule 657—6.7(124,155A) or 657—7.6(124,155A). To ensure that secure closure, the pharmacy department shall be surrounded by a physical barrier capable of being securely locked to prevent entry when the department is closed. A secure barrier may be constructed of other than a solid material with a continuous surface if the openings in the material are not large enough to permit removal of items from the pharmacy department by any means. Any material used in the construction of the barrier shall be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated, or bent.

8.5(4) *Remodel or relocation—inspection.* A pharmacy planning to remodel or relocate a licensed pharmacy department on or within the premises currently occupied by the pharmacy department, or a pharmacy intending to remodel or install a sterile compounding facility or equipment, shall provide written notification to the board at least 30 days prior to commencement of the remodel, pharmacy relocation, or sterile compounding installation. The board may require on-site inspection of the facility, equipment, or pharmacy department prior to or during the pharmacy's remodel, relocation, or opening. The board may also require on-site inspection of a temporary pharmacy location intended to be utilized during the remodel, construction, or relocation of the pharmacy department.

8.5(5) *Orderly and clean.* The pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be in good operating condition and maintained in a sanitary manner. Animals shall not be allowed within a licensed pharmacy unless that pharmacy is exclusively providing services for the treatment of animals or unless the animal is a service dog or assistive animal as defined in Iowa Code subsection 216C.11(1).

8.5(6) *Light, ventilation, temperature, and humidity.* The pharmacy shall be properly lighted and ventilated. The temperature and humidity of the pharmacy shall be maintained within a range compatible with the proper storage of drugs.

8.5(7) *Other equipment.* The pharmacist in charge and the pharmacy, by and through its owner or license holder, shall share the responsibility for ensuring the availability of any other equipment necessary for the particular practice of pharmacy and to meet the needs of the patients served by the pharmacy.

8.5(8) *Bulk counting machines.* Unless bar-code scanning is required and utilized to verify the identity of each stock container of drugs utilized to restock a counting machine cell or bin, a pharmacist shall verify the accuracy of the drugs to be restocked prior to filling the counting machine cell or bin. A record identifying the individual who verified the drugs to be restocked, the individual who restocked the counting machine cell or bin, and the date shall be maintained. Established policies and procedures shall include a method to calibrate and verify the accuracy of the counting device. The pharmacy shall, at least quarterly, verify the accuracy of the device and maintain a dated record identifying the individual who performed the quarterly verification.

8.5(9) *Authorized collection program.* A pharmacy that is registered with the DEA to administer an authorized collection program shall provide adequate space, equipment, and supplies for such collection program pursuant to 657—Chapter 10 and federal regulations for authorized collection programs, which can be found at www.deadiversion.usdoj.gov/drug_disposal/.

8.5(10) *Health of personnel.* The pharmacist in charge or supervising pharmacist shall ensure that pharmacy personnel experiencing any health condition that may have an adverse effect on drug products or may pose a health or safety risk to others be prohibited from working in the pharmacy until such health condition is sufficiently resolved. All personnel who normally assist the pharmacist shall report to the pharmacist any health conditions that may have an adverse effect on drug products or may pose a health or safety risk to others.

[**ARC 8671B**, IAB 4/7/10, effective 5/12/10; **ARC 0503C**, IAB 12/12/12, effective 1/16/13; **ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 2408C**, IAB 2/17/16, effective 3/23/16; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.6(155A) Health of personnel. Rescinded **ARC 3858C**, IAB 6/20/18, effective 7/25/18.

657—8.7(155A) Procurement, storage, and recall of drugs and devices.

8.7(1) *Source.* Procurement of prescription drugs and devices shall be from an Iowa-licensed distributor or, on a limited basis, from another licensed pharmacy or licensed practitioner located in the United States.

8.7(2) *Manner of storage.* Drugs and devices shall be stored in a manner to protect their identity and integrity.

8.7(3) *Storage temperatures.* All drugs and devices shall be stored at the proper temperature as provided in manufacturer labeling. In the absence of a specific temperature range, the pharmacy shall defer to storage conditions identified in United States Pharmacopeia chapter 659.

8.7(4) *Product recall.* There shall be a system for removing from use, including unit dose, any drugs and devices subjected to a product recall.

8.7(5) *Outdated drugs or devices.* Any drug or device bearing an expiration date shall not be dispensed for use beyond the expiration date of the drug or device. Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined until such drugs or devices are properly disposed of.

8.7(6) *Records.* All pharmacies shall maintain supplier invoices of prescription drugs and controlled substances upon which the actual date of receipt of the drugs by the pharmacist or other responsible individual is clearly recorded. All pharmacies shall maintain supplier credit memos. Pharmacy records of invoices and credit memos shall be maintained for at least two years from the date of the record. If the original supplier invoice or credit memo is received electronically, hard-copy record is not required.

[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.8(124,155A) Out-of-date drugs or devices. Rescinded **ARC 3858C**, IAB 6/20/18, effective 7/25/18.

657—8.9(124,155A) Records storage. Every record required to be maintained by a pharmacy pursuant to board rules or Iowa Code chapters 124 and 155A shall be maintained and be available for inspection and copying by the board or its representative for at least two years from the date of such record or the date of last activity on the record unless a longer retention period is specified for the particular record.

8.9(1) *Records less than 12 months old.* Records shall be maintained within the licensed pharmacy department for a minimum of 12 months, except as provided herein. Pharmacy records less than 12 months old may be stored in a secure storage area outside the licensed pharmacy department, including at a remote location, if the pharmacy has retained electronic copies of the records in the pharmacy that are immediately available and if the original records are available within 48 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

8.9(2) *Records more than 12 months old.* Records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department, including at a remote location, if the records are retrievable within 48 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

[**ARC 8539B**, IAB 2/24/10, effective 4/1/10; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.10 Reserved.

657—8.11(147,155A) Unethical conduct or practice. The provisions of this rule apply to licensed pharmacies, licensed pharmacists, registered pharmacy technicians, registered pharmacy support persons, and registered pharmacist-interns.

8.11(1) *Misrepresentative deeds.* A pharmacy, pharmacist, technician, support person, or pharmacist-intern shall not make any statement intended to deceive, misrepresent or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in pharmacy or in the operation or conduct of a pharmacy.

8.11(2) *Unethical conduct.*

a. A pharmacy, pharmacist, pharmacist-intern, technician, or support person shall not participate in any of the following types of unethical conduct:

(1) Any activity that negates a patient's freedom of choice of pharmacy services.

(2) Providing prescription blanks or forms bearing the pharmacy's name or other means of identification to any person authorized to prescribe, except that a hospital may make prescription blanks or forms bearing the hospital pharmacy's name or other means of identification available to hospital staff prescribers, emergency department prescribers, and prescribers granted hospital privileges for the prescribers' use during practice at or in the hospital.

(3) Any financial arrangement or transaction that would violate federal healthcare fraud, waste, and abuse laws, including but not limited to the Stark Law, the False Claims Act, and the Anti-Kickback Statute.

b. A purchasing pharmacist or pharmacy shall not engage in any activity or include in any agreement with a selling pharmacist or pharmacy any provision that would prevent or prohibit the prior notifications required in subrule 8.35(7).

8.11(3) *Discrimination.* A pharmacy, pharmacist, pharmacist-intern, technician, or pharmacy support person shall not discriminate between patients or groups of patients for reasons of religion, race, creed, color, gender, gender identity, sexual orientation, marital status, age, national origin, physical or mental disability, or disease state when providing pharmaceutical services.

8.11(4) *Unprofessional conduct or behavior.* A pharmacy, pharmacist, pharmacist-intern, technician, or pharmacy support person shall not engage in unprofessional behavior in connection with the practice of pharmacy. Unprofessional behavior shall include, but not be limited to, the following acts: verbal abuse, coercion, intimidation, harassment, sexual advances, threats, degradation of character, indecent or obscene conduct, theft, and the refusal to provide reasonable information or answer reasonable questions for the benefit of the patient.

[**ARC 9526B**, IAB 6/1/11, effective 7/6/11; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.12(126,147) Advertising. Prescription drug information, including price, may be provided to the public by a pharmacy so long as the information is not false or misleading and is not in violation of any federal or state laws applicable to the advertisement of such articles generally and if all of the following conditions are met:

1. All charges for services to the consumer shall be stated.
2. The effective dates for the prices listed shall be stated.
3. No reference shall be made to controlled substances listed in Schedules II through V of the latest revision of the Iowa uniform controlled substances Act and the rules of the board.

[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.13(135C,155A) Personnel histories. Pursuant to the requirements of Iowa Code section 135C.33, the provisions of this rule shall apply to any pharmacy employing any person to provide patient care services in a patient's home. For the purposes of this rule, "employed by the pharmacy" shall include any individual who is paid to provide treatment or services to any patient in the patient's home, whether the individual is paid by the pharmacy or by any other entity such as a corporation, a temporary staffing agency, or an independent contractor. Specifically excluded from the requirements of this rule are individuals such as delivery persons or couriers who do not enter the patient's home for the purpose of instructing the patient or the patient's caregiver in the use or maintenance of the equipment, device, or drug being delivered, or who do not enter the patient's home for the purpose of setting up or servicing the equipment, device, or drug used to treat the patient in the patient's home.

8.13(1) *Applicant acknowledgment.* The pharmacy shall ask the following question of each person seeking employment in a position that will provide in-home services: "Do you have a record of founded child or dependent adult abuse or have you ever been convicted of a crime, in this state or any other state?" The applicant shall also be informed that a criminal history and child and dependent adult abuse record checks will be conducted. The applicant shall indicate, by signed acknowledgment, that the applicant has been informed that such record checks will be conducted.

8.13(2) *Criminal history check.* Prior to the employment of any person to provide in-home services as described by this rule, the pharmacy shall request that the department of public safety perform a criminal history check.

8.13(3) *Abuse history checks.* Prior to the employment of any person to provide in-home services as described by this rule, the pharmacy shall request that the department of human services perform a child and dependent adult abuse record check.

a. A person who has a criminal record, founded dependent adult abuse report, or founded child abuse report shall not be employed by a pharmacy to provide in-home services unless the department of human services has evaluated the crime or founded abuse report, has concluded that the crime or founded abuse does not merit prohibition from such employment, and has notified the pharmacy that the person may be employed to provide in-home services.

b. The pharmacy shall keep copies of all record checks and evaluations for a minimum of two years following receipt of the record or for a minimum of two years after the individual is no longer employed by the pharmacy, whichever is greater.

[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.14(155A) Training and utilization of registered pharmacy staff. Pursuant to rule 657—8.3(155A), all Iowa-licensed pharmacies utilizing pharmacist-interns, pharmacy technicians, or pharmacy support persons shall have written policies and procedures for the training and utilization of pharmacist-interns, pharmacy technicians, and pharmacy support persons appropriate to the practice of pharmacy at that licensed location. Training shall be documented and maintained by the pharmacy for at least two years from the last date of employment or internship and shall be available for inspection by the board or its authorized agent.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.15(155A) Delivery of prescription drugs and devices. Prescription drug orders, prescription devices, and completed prescription drug containers may be delivered, in compliance with all laws, rules,

and regulations relating to the practice of pharmacy, to patients at any place of business licensed as a pharmacy.

8.15(1) *Alternative methods.* A licensed pharmacy may, by means of its employee or by use of a common carrier, pick up or deliver prescriptions to the patient or the patient's caregiver as follows:

a. At the office or home of the prescriber.

b. At the residence of the patient or caregiver.

c. At the hospital or medical care facility in which a patient is confined.

d. At an outpatient medical care facility where the patient receives treatment only pursuant to the following requirements:

(1) The pharmacy shall obtain and maintain the written authorization of the patient or patient's caregiver for receipt or delivery at the outpatient medical care facility;

(2) The prescription shall be delivered directly to or received directly from the patient, the caregiver, or an authorized agent identified in the written authorization;

(3) A prescription authorized by a prescriber not treating the patient at the outpatient medical care facility may be transmitted to the pharmacy by the authorized agent via facsimile provided that the means of transmission does not obscure or render the prescription information illegible due to security features of the paper utilized by the prescriber to prepare the prescription and provided that the original written prescription is delivered to the pharmacy prior to delivery of the filled prescription to the patient; and

(4) The outpatient medical care facility shall store the patient's filled prescriptions in a secure area pending delivery to the patient.

e. At the patient's or caregiver's place of employment only pursuant to the following requirements:

(1) The pharmacy shall obtain and maintain the written authorization of the patient or patient's caregiver for receipt or delivery at the place of employment;

(2) The prescription shall be delivered directly to or received directly from the patient, the caregiver, the prescriber, or an authorized agent identified in the written authorization; and

(3) The pharmacy shall ensure the security of confidential information.

8.15(2) *Policies and procedures required.* Pursuant to rule 657—8.3(155A), every pharmacy shipping or otherwise delivering prescription drugs or devices to Iowa patients shall have policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements as defined by subrule 8.7(3).

[**ARC 7636B**, IAB 3/11/09, effective 4/15/09; **ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.16(124,155A) Confidential information.

8.16(1) *Release of confidential information.* Confidential information may be released only as follows:

a. Pursuant to the express written authorization of the patient or the order or direction of a court.

b. To the patient or the patient's authorized representative.

c. To the prescriber or other licensed practitioner then caring for the patient.

d. To another licensed pharmacist when the best interests of the patient require such release.

e. To the board or its representative or to such other persons or governmental agencies duly authorized by law to receive such information.

A pharmacist shall utilize the resources available to determine, in the professional judgment of the pharmacist, that any persons requesting confidential patient information pursuant to this rule are entitled to receive that information.

8.16(2) *Exceptions.* Nothing in this rule shall prohibit a pharmacist from releasing confidential patient information as follows:

a. Transferring a prescription to another pharmacy upon the request of the patient or the patient's authorized representative or pursuant to subrule 8.35(7) when the pharmacy is discontinuing operations.

b. Providing the patient with a copy of a nonrefillable prescription that is clearly marked as a copy and not to be filled.

c. Providing drug therapy information to authorized practitioners for their patients.

d. Disclosing information necessary for the processing of third-party payer claims on behalf of the patient.

8.16(3) *Record disposal.* Disposal of any materials containing or including patient-specific or confidential information shall be conducted in a manner to preserve patient confidentiality.

[**ARC 9526B**, IAB 6/1/11, effective 7/6/11; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.17 and **8.18** Reserved.

657—8.19(124,126,155A) Manner of issuance of a prescription drug or medication order. A prescription drug order or medication order may be transmitted from a prescriber or a prescriber's agent to a pharmacy in written form, orally including telephone voice communication, by facsimile transmission as provided in rule 657—21.9(124,155A), or by electronic transmission in accordance with applicable federal and state laws, rules, and regulations. Any prescription drug order or medication order provided to a patient in written or printed form shall include the original, handwritten signature of the prescriber except as provided in rule 657—21.7(124,155A).

8.19(1) *Requirements for a prescription.* A valid prescription drug order shall be based on a valid patient-prescriber relationship except as provided in subrule 8.19(7) for epinephrine auto-injectors and in subrule 8.19(8) for opioid antagonists.

a. Written, electronic, or facsimile prescription. In addition to the electronic prescription application and pharmacy prescription application requirements of this rule, a written, electronic, or facsimile prescription shall include:

(1) The date issued.

(2) The name and address of the patient except as provided in subrule 8.19(7) for epinephrine auto-injectors and in subrule 8.19(8) for opioid antagonists.

(3) The name, strength, and quantity of the drug or device prescribed.

(4) The name and address of the prescriber and, if the prescription is for a controlled substance, the prescriber's DEA registration number.

(5) The written or electronic signature of the prescriber.

b. Written prescription. In addition to the requirements of paragraph 8.19(1)*"a,"* a written prescription shall be manually signed, with ink or indelible pencil, by the prescriber. The requirement for manual signature shall not apply when an electronically prepared and signed prescription for a noncontrolled substance is printed on security paper as provided in 657—paragraph 21.7(3)*"b."*

c. Facsimile prescription. In addition to the requirements of paragraph 8.19(1)*"a,"* a prescription transmitted via facsimile shall include:

(1) The identification number of the facsimile machine used to transmit the prescription to the pharmacy.

(2) The time and date of transmission of the prescription.

(3) The name, address, telephone number, and facsimile number of the pharmacy to which the prescription is being transmitted.

(4) If the prescription is for a controlled substance and in compliance with DEA regulations, the manual signature of the prescriber.

d. Electronic prescription. In addition to the requirements of paragraph 8.19(1)*"a,"* an electronically prepared prescription for a controlled or noncontrolled prescription drug or device that is electronically transmitted to a pharmacy shall include the prescriber's electronic signature, except as provided herein.

(1) An electronically prepared prescription for a controlled substance that is printed out or faxed by the prescriber or the prescriber's agent shall be manually signed by the prescriber.

(2) The prescriber shall ensure that the electronic prescription application used to prepare and transmit the electronic prescription complies with applicable state and federal laws, rules, and regulations regarding electronic prescriptions.

(3) The prescriber or the prescriber's agent shall provide verbal verification of an electronic prescription upon the request of the pharmacy.

(4) An electronic prescription for a noncontrolled prescription drug or device that is transmitted by an authorized agent shall not be required to contain the prescriber's electronic signature.

8.19(2) *Verification.* The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of any prescription drug order or medication order consistent with federal and state laws, rules, and regulations. In exercising professional judgment, the prescriber and the pharmacist shall take adequate measures to guard against the diversion of prescription drugs and controlled substances through prescription forgeries.

8.19(3) *Transmitting agent.* The prescriber may authorize an agent to transmit to the pharmacy a prescription drug order or medication order orally, by facsimile transmission, or by electronic transmission provided that the first and last names and title of the transmitting agent are included in the order.

a. New order. A new written or electronically prepared and transmitted prescription drug or medication order shall be manually or electronically signed by the prescriber, except as provided in paragraph 8.19(1)*"d."* If transmitted by the prescriber's agent, the first and last names and title of the transmitting agent shall be included in the order. If the prescription is for a controlled substance and is written or printed from an electronic prescription application, the prescription shall be manually signed by the prescriber. An electronically prepared prescription shall not be electronically transmitted to the pharmacy if the prescription has been printed prior to the electronic transmission. An electronically prepared and electronically transmitted prescription that is printed following the electronic transmission shall be clearly labeled as a copy, not valid for dispensing.

b. Refill order or renewal order. An authorization to refill a prescription drug or medication order, or to renew or continue an existing drug therapy, may be transmitted to professional pharmacy staff through oral communication, in writing, by facsimile transmission, or by electronic transmission initiated by or directed by the prescriber.

(1) If the transmission is completed by the prescriber's agent and the first and last names and title of the transmitting agent are included in the order, the prescriber's signature is not required on the fax or alternate electronic transmission.

(2) If the order differs in any manner from the original order, such as a change of the drug strength, dosage form, or directions for use, the prescriber shall sign the order as provided by paragraph 8.19(3)*"a."*

8.19(4) *Receiving agent.* Regardless of the means of transmission to a pharmacy, only professional pharmacy staff shall be authorized to receive a new prescription drug or medication order from a prescriber or the prescriber's agent. A technician trainee may receive a refill or renewal order from a prescriber or the prescriber's agent only if the technician's supervising pharmacist has authorized that function.

8.19(5) *Legitimate purpose.* The pharmacy and professional pharmacy staff shall ensure that the prescription drug or medication order, regardless of the means of transmission, has been issued for a legitimate medical purpose by a prescriber acting in the usual course of the prescriber's professional practice. A pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the prescription was issued solely on the basis of an Internet-based questionnaire.

8.19(6) *Refills.* A refill is one or more dispensings of a prescription drug or device that result in the patient's receipt of the quantity authorized by the prescriber for a single fill as indicated on the prescription drug order.

a. Noncontrolled prescription drug or device. A prescription for a prescription drug or device that is not a controlled substance may authorize no more than 12 refills within 18 months following the date on which the prescription is issued.

b. Controlled substance. A prescription for a Schedule III, IV, or V controlled substance may authorize no more than 5 refills within 6 months following the date on which the prescription is issued.

8.19(7) *Epinephrine auto-injector prescription issued to school or facility.* A physician, an advanced registered nurse practitioner, or a physician assistant may issue a prescription for one or more epinephrine auto-injectors in the name of a facility as defined in Iowa Code subsection 135.185(1), a school district, or an accredited nonpublic school. The prescription shall comply with all requirements of subrule 8.19(1)

as applicable to the form of the prescription except that the prescription shall be issued in the name and address of the facility, the school district, or the accredited nonpublic school in lieu of the name and address of a patient. Provisions requiring a preexisting patient-prescriber relationship shall not apply to a prescription issued pursuant to this subrule.

a. The pharmacy's patient profile and record of dispensing of a prescription issued pursuant to this subrule shall be maintained in the name of the facility, school district, or accredited nonpublic school to which the prescription was issued and the drug was dispensed.

b. The label affixed to an epinephrine auto-injector dispensed pursuant to this subrule shall identify the name of the facility, school district, or accredited nonpublic school to which the prescription is dispensed.

8.19(8) *Opioid antagonist prescription issued to law enforcement, fire department, or service program.* A physician, an advanced registered nurse practitioner, or a physician assistant may issue a prescription for one or more opioid antagonists in the name of a law enforcement agency, fire department, or service program pursuant to Iowa Code section 147A.18 and rule 657—39.7(135,147A). The prescription shall comply with all requirements of subrule 8.19(1) as applicable to the form of the prescription except that the prescription shall be issued in the name and address of the law enforcement agency, fire department, or service program in lieu of the name and address of a patient. Provisions requiring a preexisting patient-prescriber relationship shall not apply to a prescription issued pursuant to this subrule.

a. The pharmacy's patient profile and record of dispensing of an opioid antagonist pursuant to this subrule shall be maintained in the name of the law enforcement agency, fire department, or service program to which the prescription was issued and the drug was dispensed.

b. The label affixed to an opioid antagonist dispensed pursuant to this subrule shall identify the name of the law enforcement agency, fire department, or service program to which the prescription is dispensed and shall be affixed such that the expiration date of the drug is not rendered illegible.

[**ARC 8171B**, IAB 9/23/09, effective 10/28/09; **ARC 9912B**, IAB 12/14/11, effective 1/18/12; **ARC 2414C**, IAB 2/17/16, effective 3/23/16; **ARC 2827C**, IAB 11/23/16, effective 11/3/16; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.20(155A) Valid prescriber/patient relationship. Prescription drug orders and medication orders shall be valid as long as a prescriber/patient relationship exists. Once the prescriber/patient relationship is broken and the prescriber is no longer available to treat the patient or oversee the patient's use of a prescription drug, any remaining prescription refills may be dispensed at the discretion of the pharmacist for a suitable amount of time so that the patient can establish care with a new provider and a new order can be issued. In determining the duration of which prescriptions may be dispensed, the pharmacist shall consider the patient's health care status and access to health care services.

[**ARC 3639C**, IAB 2/14/18, effective 3/21/18]

657—8.21(155A) Prospective drug use review. For purposes of promoting therapeutic appropriateness and ensuring rational drug therapy, a pharmacist shall review the patient record, information obtained from the patient, and each prescription drug or medication order to identify:

1. Overutilization or underutilization;
2. Therapeutic duplication;
3. Drug-disease contraindications;
4. Drug-drug interactions;
5. Incorrect drug dosage or duration of drug treatment;
6. Drug-allergy interactions;
7. Clinical abuse/misuse;
8. Drug-prescriber contraindications.

Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem and shall, if necessary, include consultation with the prescriber. The review and assessment of patient records shall not be delegated to pharmacy technicians or pharmacy support persons but may be delegated to registered pharmacist-interns under the direct supervision of the pharmacist.

[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.22(155A) Notification of interchangeable biological product selection. Pursuant to Iowa Code section 155A.32, when a pharmacist substitutes a biological product that is an interchangeable biological product for the biological product prescribed, the pharmacist or pharmacist's designee shall, within five business days of dispensing the biological product, communicate to the prescriber the name and manufacturer of the biological product dispensed unless the prescription information has been entered into an electronic record system, such as an electronic medical record, electronic prescribing system, pharmacy benefit management system, or a pharmacy record to which the prescriber has access. The manner of communication to the prescriber may be via telephone, facsimile, electronic transmission, or other prevailing means.

This rule is intended to implement Iowa Code section 155A.32.

[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.23(124,155A) Individuals qualified to administer. Any person specifically authorized under pertinent sections of the Iowa Code to administer prescription drugs shall construe nothing in this rule to limit that authority. The board designates the following as qualified individuals to whom a prescriber may delegate the administration of prescription drugs.

1. Persons who have successfully completed a medication administration course.
2. Licensed pharmacists.

This rule is intended to implement Iowa Code section 155A.44.

[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.24(155A) Documented verification. The pharmacist shall provide, document, and retain a record of the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative. In an approved tech-check-tech program, the checking technician shall provide, document, and retain a record of the final verification for the accuracy of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative.

[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.25 Reserved.

657—8.26(155A) Continuous quality improvement program. Pursuant to rule 657—8.3(155A), each pharmacy licensed to provide pharmaceutical services to patients in Iowa shall implement or participate in a continuous quality improvement program (CQI program). The CQI program is intended to be an ongoing, systematic program of standards and procedures to detect, identify, evaluate, and prevent medication errors, thereby improving medication therapy and the quality of patient care. A pharmacy that participates as an active member of a hospital or corporate CQI program that meets the objectives of this rule shall not be required to implement a new program pursuant to this rule.

8.26(1) *Reportable program events.* For purposes of this rule, a reportable program event or program event means a preventable medication error resulting in the incorrect dispensing of a prescribed drug received by or administered to the patient and includes but is not necessarily limited to:

a. An incorrect drug;
b. An incorrect drug strength;
c. An incorrect dosage form;
d. A drug received by the wrong patient;
e. Inadequate or incorrect packaging, labeling, or directions; or
f. Any incident related to a prescription dispensed to a patient that results in or has the potential to result in serious harm to the patient.

8.26(2) *Responsibility.* The pharmacist in charge may delegate program administration and monitoring, but the pharmacist in charge maintains ultimate responsibility for the validity and consistency of program activities.

8.26(3) *Policies and procedures.* Pursuant to rule 657—8.3(155A), each pharmacy shall have written policies and procedures for the operation and management of the pharmacy's CQI program. A

copy of the pharmacy's CQI program description and policies and procedures shall be maintained and readily available to all pharmacy personnel. The policies and procedures shall address, at a minimum, a planned process to:

a. Train all pharmacy personnel in relevant phases of the CQI program;

b. Identify and document reportable program events;

c. Minimize the impact of reportable program events on patients;

d. Analyze data collected to assess the causes and any contributing factors relating to reportable program events;

e. Use the findings to formulate an appropriate response and to develop pharmacy systems and workflow processes designed to prevent and reduce reportable program events; and

f. Periodically, but at least quarterly, meet with appropriate pharmacy personnel to review findings and inform personnel of changes that have been made to pharmacy policies, procedures, systems, or processes as a result of CQI program findings.

8.26(4) *Event discovery and notification.* As provided by the procedures of the CQI program, the pharmacist in charge or appropriate designee shall be informed of and review all reported and documented program events. All pharmacy personnel shall be trained to immediately inform the pharmacist on duty of any discovered or suspected program event. When the pharmacist on duty determines that a reportable program event has occurred, the pharmacist shall ensure that all reasonably necessary steps are taken to remedy any problems or potential problems for the patient and that those steps are documented. Necessary steps include, but are not limited to, the following:

a. Notifying the patient or the patient's caregiver and the prescriber or other members of the patient's health care team as warranted;

b. Identifying and communicating directions or processes for correcting the error; and

c. Communicating instructions for minimizing any negative impact on the patient.

8.26(5) *CQI program records.* All CQI program records shall be maintained on site at the pharmacy or shall be accessible at the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of the record. When a reportable program event occurs or is suspected to have occurred, the program event shall be documented in a written or electronic storage record created solely for that purpose. Records of program events shall be maintained in an orderly manner and shall be filed chronologically by date of discovery.

a. The program event shall initially be documented as soon as practicable but no more than three days following discovery of the event by the staff member who discovers the event or is informed of the event.

b. Program event documentation shall include a description of the event that provides sufficient information to permit categorization and analysis of the event and shall include:

(1) The date and time the program event was discovered and the name of the staff person who discovered the event; and

(2) The names of the individuals recording and reviewing or analyzing the program event information.

8.26(6) *Program event analysis and response.* The pharmacist in charge or designee shall review each reportable program event and determine if follow-up is necessary. When appropriate, information and data collected and documented shall be analyzed, individually and collectively, to assess the cause and any factors contributing to the program event. The analysis may include, but is not limited to, the following:

a. A consideration of the effects on the quality of the pharmacy system related to workflow processes, technology utilization and support, personnel training, and both professional and technical staffing levels;

b. Any recommendations for remedial changes to pharmacy policies, procedures, systems, or processes; and

c. The development of a set of indicators that a pharmacy will utilize to measure its program standards over a designated period of time.

[**ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 2413C**, IAB 2/17/16, effective 3/23/16; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.27 to **8.29** Reserved.

657—8.30(126,155A) Sterile products. Rescinded IAB 6/6/07, effective 7/11/07.

657—8.31(135,147A) Opioid antagonist dispensing by pharmacists by standing order. Rescinded **ARC 3858C**, IAB 6/20/18, effective 7/25/18.

657—8.32(124,155A) Individuals qualified to administer. Rescinded **ARC 3858C**, IAB 6/20/18, effective 7/25/18.

657—8.33(155A) Vaccine administration by pharmacists. Rescinded **ARC 3858C**, IAB 6/20/18, effective 7/25/18.

657—8.34(155A) Collaborative drug therapy management. Rescinded **ARC 3858C**, IAB 6/20/18, effective 7/25/18.

657—8.35(155A) Pharmacy license. A pharmacy license issued by the board is required for all sites where prescription drugs are offered for sale or dispensed under the supervision of a pharmacist. The current pharmacy license certificate shall be displayed in a position visible to the public. The board may issue any of the following types of pharmacy licenses: a general pharmacy license, a hospital pharmacy license, a limited use pharmacy license, or a nonresident pharmacy license. Nonresident pharmacy license applicants shall comply with board rules regarding nonresident pharmacy practice except when a waiver has been granted. Applicants for general or hospital pharmacy practice shall comply with board rules regarding general or hospital pharmacy practice except when a waiver has been granted. Any pharmacy that dispenses controlled substances to Iowa residents must also register pursuant to 657—Chapter 10.

8.35(1) *Limited use pharmacy license.* A limited use pharmacy license may be issued for nuclear pharmacy practice, correctional facility pharmacy practice, veterinary pharmacy practice, telepharmacy practice, and other limited use practice settings. Applications for a limited use pharmacy license shall be considered on a case-by-case basis.

8.35(2) *Application.* Applicants for initial licensure, license renewal, license reactivation, or license changes pursuant to subrule 8.35(6) shall complete the relevant pharmacy license application and shall include all required information and attachments. All pharmacy license applications require submission of a nonrefundable $135 license fee plus applicable penalty fees. The application shall include the signature of the pharmacy owner's authorized representative and shall require at a minimum the following:

a. Disclosure of pharmacy ownership information, including information about the pharmacy's registered agent;

b. Identification and signature of the pharmacist in charge;

c. The identification of and average number of hours worked by all pharmacists, pharmacist-interns, pharmacy technicians, and pharmacy support persons working in the pharmacy;

d. Criminal and disciplinary history information; and

e. Description of the scope of services provided by the pharmacy.

8.35(3) *License renewal.* A pharmacy license shall be renewed before January 1 of each year. An initial pharmacy license issued between November 1 and December 31 shall not require renewal until the following calendar year. The nonrefundable fee for a timely license renewal shall be $135.

a. Delinquent license grace period. A pharmacy license renewal application that is postmarked or hand-delivered to the board after January 1 but prior to February 1 following expiration shall be

considered delinquent and shall require the nonrefundable payment of the renewal fee plus a penalty fee of $135. A pharmacy that submits a completed license renewal application, application fee, and penalty fee postmarked or delivered to the board office by January 31 shall not be subject to disciplinary action for continuing to operate in the month of January.

b. Delinquent license reactivation beyond grace period. If a pharmacy license is not renewed prior to the expiration of the one-month grace period identified in paragraph 8.35(3)*"a,"* the pharmacy may not operate or provide pharmacy services to patients in the state of Iowa until the license is reactivated. A pharmacy without a current license may apply for license reactivation by submitting an application for reactivation and a nonrefundable $540 reactivation fee. As part of the reactivation application, the pharmacy shall disclose the prescriptions dispensed and the services, if any, that were provided to Iowa patients while the license was delinquent. A pharmacy that continues to operate or provide pharmacy services in Iowa without a current license may be subject to disciplinary sanctions.

8.35(4) *Inspection of new pharmacy location.* A new pharmacy location in Iowa shall require an on-site inspection by an authorized agent of the board. Application for a pharmacy license and other required registrations shall be submitted to the board at least 14 days prior to the anticipated inspection. Any deficiencies identified during the inspection shall be corrected and verified by an authorized agent of the board prior to the issuance of the pharmacy license. Prescription drugs, including controlled substances, may not be delivered to a new pharmacy location prior to the delivery of the pharmacy license and registration certificates.

8.35(5) *Failure to complete licensure.* An application for a pharmacy license, including any other required registration applications, will become null and void if the applicant fails to complete the licensure process within six months of acceptance by the board of the required applications. The licensure process shall be complete upon the pharmacy's opening for business at the licensed location following a satisfactory inspection by an agent of the board pursuant to this rule. When an applicant fails to timely complete the licensure process, fees submitted with applications will not be transferred or refunded. If the applicant intends to proceed with a pharmacy license, a new application and fee shall be required.

8.35(6) *Pharmacy license changes.* When a pharmacy changes its name, location, ownership, or pharmacist in charge, a completed pharmacy license application with a nonrefundable $135 fee shall be submitted to the board. Upon receipt of the completed application and fee, the board shall issue an updated pharmacy license certificate unless the board identifies any ground for denial of the license. Any restrictions or disciplinary history associated with the previous pharmacy shall remain unchanged. A pharmacy wishing to disassociate itself from the previously licensed pharmacy restrictions or disciplinary history may petition the board for such disassociation. The burden is on the pharmacy to demonstrate that the current pharmacy is not associated with or responsible for the pharmacy as it previously existed. The old license certificate shall be returned to the board within ten days of receiving the updated license certificate.

a. Name. A change of the name under which the pharmacy is doing business shall require submission of a pharmacy license application and appropriate fee prior to the change of name.

b. Location. A change of pharmacy location shall require submission of a pharmacy license application and appropriate fee prior to the change of location. A pharmacy undergoing a change in location is required to notify patients of the change in accordance with paragraph 8.35(7)*"d."* A change of pharmacy location in Iowa may require an on-site inspection of the new location as provided in subrule 8.35(4).

c. Ownership. A change in ownership of a pharmacy shall require submission of a pharmacy license application and appropriate fee prior to the change in ownership. A change of ownership occurs when the owner listed on the pharmacy's most recent application changes or when there is a change affecting the majority ownership interest of the owner listed on the pharmacy's most recent pharmacy application. A pharmacy undergoing a change in ownership is required to notify the pharmacist in charge and patients of the change in accordance with subrule 8.35(7). A change of ownership effectively consists of closing a pharmacy and opening a new pharmacy.

d. Pharmacist in charge. In addition to the requirements of this paragraph, a change of pharmacist in charge for a nonresident pharmacy shall require registration of the new permanent pharmacist in charge if the pharmacist in charge is not currently registered by the board or licensed to practice pharmacy in Iowa.

(1) If a permanent pharmacist in charge has been identified by the time of the vacancy, a pharmacy license application identifying the new pharmacist in charge, along with the appropriate fee, shall be submitted to the board within ten days of the change.

(2) If a permanent pharmacist in charge has not been identified by the time of the vacancy, a temporary pharmacist in charge shall be identified. Written notification identifying the temporary pharmacist in charge shall be submitted to the board within ten days of the vacancy.

(3) If a permanent pharmacist in charge was not identified within ten days of the vacancy, the pharmacy shall, within 90 days of the vacancy, identify a permanent pharmacist in charge. A pharmacy license application identifying the permanent pharmacist in charge, along with appropriate fee, shall be submitted to the board within ten days of the appointment of a permanent pharmacist in charge. The pharmacy license application and the pharmacist in charge registration application, if needed, including appropriate fees, shall be received by the board within 90 days of the original vacancy of the permanent pharmacist in charge position.

8.35(7) *Closing or sale of a pharmacy.* A closing pharmacy shall ensure that all pharmacy records are transferred to another licensed pharmacy that agrees to act as custodian of the records for at least two years. A pharmacy shall not execute a sale or closing of a pharmacy unless there exists an adequate period of time prior to the pharmacy's closing for delivery of the notifications to the pharmacist in charge, the board, the DEA, and pharmacy patients as required by this subrule. However, the provisions of this subrule regarding prior notifications to the board, the DEA, and patients shall not apply in the case of a board-approved emergency or unforeseeable closure, including but not limited to emergency board action, foreclosure, fire, or natural disaster.

a. Pharmacist in charge notification. At least 40 days prior to the effective date of the sale or closing of a pharmacy, the pharmacist in charge of the closing pharmacy shall be notified of the proposed sale or closing. Information regarding the pending sale or closure of the pharmacy may be kept confidential until public notifications, which are required 30 days prior to the pharmacy's closing, are made. The pharmacist in charge of the closing pharmacy shall provide input and direction to the pharmacy owner regarding the responsibilities of the closing pharmacy, including the notifications, deadlines, and timelines established by this subrule. The pharmacist in charge of the purchasing or receiving pharmacy shall be notified of the pending transaction at least 30 days prior to the sale or closure of the pharmacy.

b. Board and DEA notifications. At least 30 days prior to the closing of a pharmacy, a written notice shall be sent to the board. Notification to the DEA shall be pursuant to federal regulation. Notification to the board shall include:

(1) The anticipated date of closing or transfer of prescription drugs or records.

(2) The name, address, DEA registration number, Iowa pharmacy license number, and Iowa controlled substances Act (CSA) registration number of the closing pharmacy and of the pharmacy to which prescription drugs will be transferred.

(3) The name, address, DEA registration number, Iowa pharmacy license number, and CSA registration number of the location at which records will be maintained.

c. Terms of sale or purchase. If the closing is due to the sale of the pharmacy, a copy of the sale or purchase agreement, not including information regarding the monetary terms of the transaction, shall be submitted to the board upon the request of the board. The agreement shall include a written assurance from the closing pharmacy to the purchasing pharmacy that the closing pharmacy has given or will be giving notice to its patients as required by this subrule.

d. Patient notification. At least 30 days prior to closing, a closing pharmacy shall make a reasonable effort to notify all patients who had a prescription filled by the closing pharmacy within the last 18 months that the pharmacy intends to close, including the anticipated closing date.

(1) Written notification shall identify the pharmacy that will be receiving the patient's records. The notification shall advise patients that all patient records will be transferred to the identified pharmacy and that patients may contact the closing pharmacy to request the transfer of remaining refills to a pharmacy of the patient's choice. The notification shall also advise patients that after the date of closing, patients may contact the pharmacy to which the records have been transferred.

(2) Written notification shall be delivered to each patient at the patient's last address on file with the closing pharmacy by direct mail or personal delivery. A pharmacy shall not be required to provide written notice to more than one patient within the same household.

(3) Public notice shall be provided in a location and manner clearly visible to patients in the pharmacy pickup locations including drive-through prescription pickup lanes, on pharmacy or retail store entry and exit doors, and at pharmacy prescription counters.

e. Patient communication by receiving pharmacy. A pharmacy receiving the patient records of another pharmacy shall not contact the patients of the closing pharmacy until after the transfer of those patient records from the closing pharmacy to the receiving pharmacy and after the closure of the closing pharmacy.

f. Prescription drug inventory. A complete inventory of all prescription drugs being transferred shall be taken as of the close of business. The inventory shall serve as the ending inventory for the closing pharmacy as well as a record of additional or starting inventory for the pharmacy to which the drugs are transferred. A copy of the inventory shall be maintained in the records of the purchasing pharmacy for at least two years.

(1) DEA Form 222 is required for transfer of Schedule II controlled substances.

(2) The inventory of controlled substances shall be completed pursuant to the requirements in rule 657—10.19(124).

(3) The inventory of all noncontrolled prescription drugs shall include the name, strength, dosage form, and quantity, which may be estimated.

(4) Controlled substances and prescription drugs requiring destruction or other disposal shall be transferred in the same manner as all other drugs. The new owner is responsible for the disposal of these drugs.

g. Return of certificates and forms. The pharmacy license certificate and CSA registration certificate of the closing or selling pharmacy shall be returned to the board within ten days of closing or sale. The pharmacy shall be responsible for complying with federal DEA regulations for the cancellation and return of DEA forms and certificates.

h. Signs at closed pharmacy location. A location that no longer houses a licensed pharmacy shall not display any sign, placard, or other notification, visible to the public, which identifies the location as a pharmacy. A sign or other public notification that cannot feasibly be removed shall be covered so as to conceal the identification as a pharmacy. Nothing in this paragraph shall prohibit the display of a public notice to patients, as required in paragraph 8.35(7)*"d,"* for a reasonable period not to exceed six months following the pharmacy's closing.

8.35(8) *Reporting discipline and criminal convictions.* A pharmacy shall, no later than 30 days after the final action, provide written notice to the board of any discipline imposed by any licensing authority on any license or registration held by the pharmacy. Discipline may include, but is not limited to, fine or civil penalty, citation or reprimand, probationary period, suspension, revocation, or voluntary surrender. A pharmacy shall, no later than 30 days after a conviction, provide written notice to the board of any criminal conviction of the pharmacy or of any pharmacy owner when that conviction is related to prescription drugs or to the operation of the pharmacy. The term criminal conviction includes instances when the judgment of conviction or sentence is deferred.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9526B**, IAB 6/1/11, effective 7/6/11 (See Delay note at end of chapter); **ARC 9693B**, IAB 9/7/11, effective 8/11/11; **ARC 0504C**, IAB 12/12/12, effective 1/16/13; **ARC 1962C**, IAB 4/15/15, effective 5/20/15; **ARC 3236C**, IAB 8/2/17, effective 9/6/17; **ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.36 to **8.39** Reserved.

657—8.40(155A,84GA,ch63) Pharmacy pilot or demonstration research projects. Rescinded **ARC 3858C**, IAB 6/20/18, effective 7/25/18.

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CHAPTER 10
CONTROLLED SUBSTANCES
[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 8]

657—10.1(124) Purpose and scope. This chapter establishes the minimum standards for any activity that involves controlled substances. Any person or business that manufactures; distributes; dispenses; prescribes; conducts instructional activities, research, or chemical analysis with; or imports or exports controlled substances listed in Schedules I through V of Iowa Code chapter 124 in or into the state of Iowa, or that proposes to engage in such activities, shall obtain and maintain a registration issued by the board unless exempt from registration pursuant to rule 657—10.8(124). A person or business required to be registered shall not engage in any activity for which registration is required until the application for registration is granted and the board has issued a certificate of registration to such person or business. A registration is not transferable to any person or business.
[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.2(124) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Authorized collection program" means a program administered by a registrant that has modified its registration with DEA to collect controlled substances for the purpose of disposal. Federal regulations for such programs can be found at www.deadiversion.usdoj.gov/drug_disposal/. Modification to the registrant's Iowa controlled substances Act registration shall not be required.

"Board" means the Iowa board of pharmacy.

"CSA" means the Iowa uniform controlled substances Act.

"CSA registration" or *"registration"* means the registration issued by the board pursuant to the CSA that signifies the registrant's authorization to engage in registered activities with controlled substances.

"DEA" means the United States Department of Justice, Drug Enforcement Administration.

"Individual practitioner" means a physician or surgeon (M.D.), osteopathic physician or surgeon (D.O.), dentist (D.D.S. or D.M.D.), doctor of veterinary medicine (D.V.M.), podiatric physician (D.P.M.), optometrist (O.D.), physician assistant (P.A.), resident physician, advanced registered nurse practitioner (A.R.N.P.), or prescribing psychologist.
[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.3(124) Who shall register. The following persons or businesses shall register on forms provided by the board:

1. Manufacturers, distributors, importers, and exporters located in Iowa. Effective January 1, 2018, nonresident manufacturers, distributors, importers, and exporters distributing controlled substances into Iowa.
2. Reverse distributors located in Iowa. Effective January 1, 2018, nonresident reverse distributors engaging in the transfer of controlled substances with registrants located in Iowa.
3. Individual practitioners located in Iowa who are administering, dispensing, or prescribing controlled substances and individual practitioners located outside of Iowa who are dispensing or prescribing controlled substances via telehealth services to patients located in Iowa.
4. Pharmacies located in Iowa that are dispensing controlled substances. Effective January 1, 2018, pharmacies located outside of Iowa that are delivering controlled substances to patients located in Iowa.
5. Hospitals located in Iowa that are administering or dispensing controlled substances. Effective January 1, 2018, hospitals located outside of Iowa that are administering or dispensing controlled substances to patients located in Iowa.
6. Emergency medical service programs that are administering controlled substances to patients located in Iowa.
7. Care facilities that are located in Iowa.
8. Researchers, analytical laboratories, and teaching institutions that are located in Iowa.
9. Animal shelters and dog training facilities that are located in Iowa.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.4 Reserved.

657—10.5(124) Application. Applicants for initial registration, registration renewal pursuant to rule 657—10.6(124), or modifications pursuant to rule 657—10.9(124) shall complete the appropriate application and shall include all required information and attachments. Each registration application shall require submission of a $90 registration fee except as provided in subrule 10.5(3).

10.5(1) *Signature requirements.* Each application, attachment, or other document filed as part of an application shall be signed by the applicant as follows:

a. If the applicant is an individual practitioner, the practitioner shall sign the application and supporting documents.

b. If the applicant is a business, the application and supporting documents shall be signed by the person ultimately responsible for the security and maintenance of controlled substances at the registered location.

10.5(2) *Submission of multiple applications.* Any person or business required to obtain more than one registration pursuant to rule 657—10.7(124) or 657—10.8(124) may submit all applications in one package. Each application shall be complete and shall not refer to any accompanying application or any attachment to an accompanying application for required information.

10.5(3) *Registration fee exemptions.* The registration fee is waived for federal, state, and local law enforcement agencies and for the following federal and state institutions: hospitals, health care or teaching institutions, and analytical laboratories authorized to possess, manufacture, distribute, and dispense controlled substances in the course of official duties. In order to enable law enforcement agency laboratories to obtain and transfer controlled substances for use as standards in chemical analysis, such laboratories shall maintain a registration to conduct chemical analysis (analytical laboratory). Such laboratories shall be exempt from any registration fee. Exemption from payment of any fees as provided in this subrule does not relieve the entity of registration or of any other requirements or duties prescribed by law.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.6(124) Registration renewal. Each registration shall be renewed prior to its biennial expiration. A registrant may renew its registration up to 60 days prior to the registration expiration. The fee for registration renewal shall be $90.

10.6(1) *Delinquent registration grace period.* A registration that is not renewed prior to the first day of the month following expiration shall be delinquent. A registrant may continue operations within the first 30 days following expiration while the license is delinquent if the registrant is in the process of renewing the registration. Failure to renew a registration prior to the first day of the month following expiration, but when submitting a completed renewal application within the 30 days following expiration, shall require payment of the renewal fee and a penalty fee of $90.

10.6(2) *Delinquent registration reactivation beyond grace period.* If a registration renewal application is not postmarked or hand-delivered to the board office within 30 days following its expiration date, the registrant may not conduct operations that involve controlled substances until the registrant reactivates the registration. A registrant may apply for reactivation by submitting a registration application for reactivation and a $360 fee. As part of the reactivation application, the registrant shall disclose the activities conducted with respect to controlled substances while the registration was expired. A registrant that continues to conduct activities with respect to controlled substances without an active registration may be subject to disciplinary sanctions.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.7(124) Separate registration for independent activities; coincident activities. The following activities are deemed to be independent of each other and shall require separate registration. Any person or business engaged in more than one of these activities shall be required to separately register for each independent activity, provided, however, that registration in an independent activity shall authorize the registrant to engage in activities identified coincident with that independent activity.

10.7(1) *Manufacturing controlled substances.* A person or business registered to manufacture controlled substances in Schedules I through V may distribute any substances for which registration to manufacture was issued. A person or business registered to manufacture controlled substances in Schedules II through V may conduct chemical analysis and preclinical research, including quality control analysis, with any substances listed in those schedules for which the person or business is registered to manufacture.

10.7(2) *Distributing controlled substances.* This independent activity includes the delivery, other than by administering or dispensing, of controlled substances listed in Schedules I through V. No coincident activities are authorized.

10.7(3) *Dispensing, administering, prescribing, or instructing with controlled substances.* These independent activities include, but are not limited to, prescribing, administering, and dispensing by individual practitioners; dispensing by pharmacies and hospitals; and conducting instructional activities with controlled substances listed in Schedules II through V. A person or business registered for these independent activities may conduct research and instructional activities with those substances for which the person or business is registered to the extent authorized under state law. If an entity that engages in the distribution, administration, dispensing, or storing of controlled substances maintains multiple licenses, such as a hospital that has both inpatient and outpatient pharmacies, a separate registration shall be maintained for each license.

10.7(4) *Conducting research with controlled substances listed in Schedule I.* A researcher may manufacture or import the substances for which registration was issued provided that such manufacture or import is permitted under the federal DEA registration. A researcher may distribute the substances for which registration was issued to persons or businesses registered or authorized to conduct research with that class of substances or registered or authorized to conduct chemical analysis with controlled substances.

10.7(5) *Conducting research with controlled substances listed in Schedules II through V.* A researcher may conduct chemical analysis with controlled substances in those schedules for which registration was issued, may manufacture such substances if and to the extent such manufacture is permitted under the federal DEA registration, and may import such substances for research purposes. A researcher may distribute controlled substances in those schedules for which registration was issued to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances, and to persons exempt from registration pursuant to Iowa Code section 124.302(3), and may conduct instructional activities with controlled substances.

10.7(6) *Conducting chemical analysis with controlled substances.* A person or business registered to conduct chemical analysis with controlled substances listed in Schedules I through V may manufacture and import controlled substances for analytical or instructional activities; may distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempt from registration pursuant to Iowa Code section 124.302(3); may export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries; and may conduct instructional activities with controlled substances.

10.7(7) *Importing or exporting controlled substances.* A person or business registered to import controlled substances listed in Schedules I through V may distribute any substances for which such registration was issued.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.8(124) Separate registrations for separate locations; exemption from registration. A separate registration is required for each principal place of business or professional practice location where controlled substances are manufactured, distributed, imported, exported, dispensed, stored, or collected for the purpose of disposal unless the person or business is exempt from registration pursuant to Iowa Code section 124.302(3), this rule, or federal regulations.

10.8(1) *Warehouse.* A warehouse where controlled substances are stored by or on behalf of a registered person or business shall be exempt from registration except as follows:

a. Registration of the warehouse shall be required if such controlled substances are distributed directly from that warehouse to registered locations other than the registered location from which the substances were delivered to the warehouse.

b. Registration of the warehouse shall be required if such controlled substances are distributed directly from that warehouse to persons exempt from registration pursuant to Iowa Code section 124.302(3).

10.8(2) *Sales office.* An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised shall be exempt from registration. Such office shall not contain controlled substances, except substances used for display purposes or for lawful distribution as samples, and shall not serve as a distribution point for filling sales orders.

10.8(3) *Prescriber's office.* An office used by a prescriber who is registered at another location and where controlled substances are prescribed but where no supplies of controlled substances are maintained shall be exempt from registration. However, a prescriber who practices at more than one office location where controlled substances are administered or otherwise dispensed as a regular part of the prescriber's practice shall register at each location wherein the prescriber maintains supplies of controlled substances.

10.8(4) *Prescriber in hospital.* A prescriber who is registered at another location and who treats patients and may order the administration of controlled substances in a hospital other than the prescriber's registered practice location shall not be required to obtain a separate registration at the location of the hospital.

10.8(5) *Affiliated interns, residents, or foreign physicians.* An individual practitioner who is an intern, resident, or foreign physician may dispense and prescribe controlled substances under the registration of the hospital or other institution which is registered and by whom the practitioner is employed provided that:

a. The hospital or other institution by which the individual practitioner is employed has determined that the practitioner is permitted to dispense or prescribe drugs by the appropriate licensing board.

b. Such individual practitioner is acting only in the scope of employment or practice in the hospital, institution, internship program, or residency program.

c. The hospital or other institution authorizes the intern, resident, or foreign physician to dispense or prescribe under the hospital registration and designates a specific internal code number, letters, or combination thereof which shall be appended to the institution's DEA registration number, preceded by a hyphen (e.g., AP1234567-10 or AP1234567-12).

d. The hospital or institution maintains a current list of internal code numbers identifying the corresponding individual practitioner, available for the purpose of verifying the authority of the prescribing individual practitioner.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.9(124) Modification or termination of registration. A registered individual or business shall apply to modify a current registration as provided by this rule.

10.9(1) *Change of substances authorized.* Any registrant shall apply to modify the substances authorized by the registration by submitting a written request to the board. The request shall include the registrant's name, address, telephone number, registration number, and the substances or schedules to be added to or removed from the registration and shall be signed by the same person who signed the most recent application for registration or registration renewal. No fee shall be required for the modification.

10.9(2) *Change of address of registered location.*

a. Individual practitioner or researcher. An entity registered as an individual practitioner or researcher shall apply to change the address of the registered location by submitting a written request to the board. The request shall include the registrant's name, current address, new address, telephone number, effective date of the address change, and registration number, and shall be signed by the registered individual practitioner or the same person who signed the most recent application for registration or registration renewal. No fee shall be required for the modification.

b. Pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter. An entity registered as a pharmacy, hospital, care

facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter shall apply to change the address of the registered location by submitting a completed application and fee for registration as provided in rule 657—10.5(124).

10.9(3) *Change of registrant's name.*

a. Individual practitioner or researcher. An entity registered as an individual practitioner or researcher shall apply to change the registrant's name by submitting a written request to the board. The request shall include the registrant's current name, new name, address, telephone number, effective date of the name change, and registration number, and shall be signed by the registered individual practitioner or the same person who signed the most recent application for registration or registration renewal. No fee shall be required for the modification. Change of name, as used in this paragraph, refers to a change of the legal name of the registrant and does not authorize the transfer of a registration issued to an individual practitioner or researcher to another individual practitioner or researcher.

b. Pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter. An entity registered as a pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter shall apply to change the registrant name by submitting a completed application and fee for registration as provided in rule 657—10.5(124).

10.9(4) *Change of ownership of registered business entity.* A change of immediate ownership of a pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter shall require the submission of a completed application and fee for registration as provided in rule 657—10.5(124).

10.9(5) *Change of responsible individual.* Any registrant, except an individual practitioner or researcher or a pharmacy or hospital, shall apply to change the responsible individual authorized by the registration by submitting a written request to the board. The request shall include the registrant's name, address, and telephone number; the name and title of the current responsible individual and of the new responsible individual; the effective date of the change; and the registration number and shall be signed by the new responsible individual. No fee shall be required for the modification.

a. Individual practitioners and researchers. Responsibility under a registration issued to an individual practitioner or researcher shall remain with the named individual practitioner or researcher. The responsible individual under such registration may not be changed or transferred.

b. Pharmacies and hospitals. The responsible pharmacist may execute a power of attorney for DEA order forms to change responsibility under the registration issued to the pharmacy or hospital. The power of attorney shall include the name, address, DEA registration number, and CSA registration number of the registrant. The power of attorney shall identify the current and new responsible individuals and shall authorize the new responsible individual to execute applications and official DEA order forms to requisition Schedule II controlled substances. The power of attorney shall be signed by both individuals, shall be witnessed by two adults, and shall be maintained by the registrant and available for inspection or copying by representatives of the board or other state or federal authorities. The responsible individual may be changed on the CSA registration by submission of a completed application and fee for registration as provided in rule 657—10.5(124).

10.9(6) *Termination of registration.* A registration issued to an individual or business shall terminate when the registered individual or business ceases legal existence, discontinues business, or discontinues professional practice. A registration issued to an individual shall terminate upon the death of the individual.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.10(124) Denial, modification, suspension, or revocation of registration.

10.10(1) *Grounds for suspension or revocation.* The board may suspend or revoke any registration upon a finding that the registrant:

a. Has furnished false or fraudulent material information in any application filed under this chapter.

b. Has had the registrant's federal registration to manufacture, distribute, or dispense controlled substances suspended or revoked.

c. Has been convicted of a public offense under any state or federal law relating to any controlled substance. For the purpose of this rule only, a conviction shall include a plea of guilty, a forfeiture of bail or collateral deposited to secure a defendant's appearance in court which forfeiture has not been vacated, or a finding of guilt in a criminal action even though entry of the judgment or sentence has been withheld and the individual has been placed on probation.

d. Has committed such acts as would render the registrant's registration under Iowa Code section 124.303 inconsistent with the public interest as determined by that section.

e. Has been subject to discipline by the registrant's respective professional licensing board and the discipline revokes or suspends the registrant's professional license or otherwise disciplines the registrant's professional license in a way that restricts the registrant's authority to handle or prescribe controlled substances. A copy of the record of licensee discipline or a copy of the licensee's surrender of the professional license shall be conclusive evidence.

10.10(2) *Limited suspension or revocation.* If the board finds grounds to suspend or revoke a registration, the board may limit revocation or suspension of the registration to the particular controlled substance, substances, or schedules with respect to which the grounds for revocation or suspension exist. If the revocation or suspension is limited to a particular controlled substance, substances, or schedules, the registrant shall be given a new certificate of registration reflecting the restrictions imposed by the revocation or suspension; no fee shall be required for the new certificate of registration. The registrant shall deliver the old certificate of registration to the board.

10.10(3) *Denial of registration or registration renewal.* If, upon examination of an application for registration or registration renewal, including any other information the board has or receives regarding the applicant, the board determines that the issuance of the registration would be inconsistent with the public interest, the board shall serve upon the applicant an order to show cause why the registration should not be denied.

10.10(4) *Considerations in denial of registration.* In determining the public interest, the board shall consider all of the following factors:

a. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels.

b. Compliance with applicable state and local law.

c. Any convictions of the applicant under any federal and state laws relating to any controlled substance.

d. Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion.

e. Furnishing by the applicant of false or fraudulent material in any application filed under this chapter.

f. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law.

g. Any other factors relevant to and consistent with the public health and safety.

10.10(5) *Order to show cause.* Before denying, modifying, suspending, or revoking a registration, the board shall serve upon the applicant or registrant an order to show cause why the registration should not be denied, modified, revoked, or suspended. The order to show cause shall contain a statement of the basis therefore and shall call upon the applicant or registrant to appear before an administrative law judge or the board at a time and place not less than 30 days after the date of service of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, suspension, or modification of registration and a summary of the matters of fact and law asserted. If the order to show cause involves the possible denial of registration renewal, the order shall be served not later than 30 days before the expiration of the registration. Proceedings to refuse renewal of registration shall not abate the existing registration, which shall remain in effect pending the outcome of the administrative hearing unless the board issues an order of immediate suspension pursuant to subrule 10.10(9).

10.10(6) *Hearing requested.* If an applicant or registrant that has received an order to show cause desires a hearing on the matter, the applicant or registrant shall file a request for a hearing within 30

days after the date of service of the order to show cause. If a hearing is requested, the board shall hold a hearing pursuant to 657—Chapter 35 at the time and place stated in the order and without regard to any criminal prosecution or other proceeding. Unless otherwise ordered by the board, an administrative law judge employed by the department of inspections and appeals shall be assigned to preside over the case and to draft a proposed decision for the board's consideration.

10.10(7) *Waiver of hearing.* If an applicant or registrant entitled to a hearing on an order to show cause fails to file a request for hearing, or if the applicant or registrant requests a hearing but fails to appear at the hearing, the applicant or registrant shall be deemed to have waived the opportunity for a hearing unless the applicant or registrant shows good cause for such failure.

10.10(8) *Final board order when hearing waived.* If an applicant or registrant entitled to a hearing waives or is deemed to have waived the opportunity for a hearing, the executive director of the board may cancel the hearing and issue, on behalf of the board, the board's final order on the order to show cause.

10.10(9) *Order of immediate suspension.* The board may suspend any registration simultaneously with the service upon the registrant of an order to show cause why such registration should not be revoked or suspended if the board finds there is an imminent danger to the public health or safety that warrants such action. If the board suspends a registration simultaneously with the service of the order to show cause upon the registrant, it shall serve upon the registrant with the order to show cause an order of immediate suspension containing a statement of its findings regarding the danger to public health or safety. The suspension shall continue in effect until the conclusion of the proceedings, including judicial review thereof, under the provisions of the Iowa administrative procedure Act, unless sooner withdrawn by the board or dissolved by the order of the district court or an appellate court.

10.10(10) *Disposition of controlled substances.* If the board suspends or revokes a registration, the registrant shall promptly return the certificate of registration to the board. Also, upon service of the order of the board suspending or revoking the registration, the registrant shall deliver all affected controlled substances in the registrant's possession to the board or authorized agent of the board. Upon receiving the affected controlled substances from the registrant, the board or its authorized agent shall place all such substances under seal and retain the sealed controlled substances pending final resolution of any appeals or until a court of competent jurisdiction directs otherwise. No disposition may be made of the substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application, orders the sale of perishable substances and the deposit of proceeds of the sale with the court. Upon a revocation order's becoming final, all such controlled substances may be forfeited to the state.

10.10(11) *Notifications.* The board shall promptly notify the DEA and the Iowa department of public safety of all orders suspending or revoking registration and all forfeitures of controlled substances.
[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.11 Reserved.

657—10.12(124) Inspection. The board may inspect, or cause to be inspected, the establishment of an applicant or registrant. The board shall review the application for registration and other information regarding an applicant or registrant in order to determine whether the applicant or registrant has met the applicable standards of Iowa Code chapter 124 and these rules.
[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.13(124) Security requirements. All registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the board shall use the security requirements set forth in these rules as standards for the physical security controls and operating procedures necessary to prevent diversion.

10.13(1) *Physical security.* Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operation. A

registrant shall periodically review and adjust security measures based on rescheduling of substances or changes in the quantity of substances in the possession of the registrant.

a. Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet or safe.

b. Controlled substances listed in Schedules II through V may be stored in a securely locked, substantially constructed cabinet or safe. However, pharmacies and hospitals may disperse these substances throughout the stock of noncontrolled substances in a manner so as to obstruct the theft or diversion of the controlled substances.

c. Controlled substances collected via an authorized collection program for the purpose of disposal shall be stored pursuant to federal regulations, which can be found at www.deadiversion.usdoj.gov/drug_disposal/.

10.13(2) *Factors in evaluating physical security systems.* In evaluating the overall security system of a registrant or applicant necessary to maintain effective controls against theft or diversion of controlled substances, the board may consider any of the following factors it deems relevant to the need for strict compliance with the requirements of this rule:

a. The type of activity conducted.

b. The type, form, and quantity of controlled substances handled.

c. The location of the premises and the relationship such location bears to security needs.

d. The type of building construction comprising the facility and the general characteristics of the building or buildings.

e. The type of vault, safe, and secure enclosures available.

f. The type of closures on vaults, safes, and secure enclosures.

g. The adequacy of key control systems or combination lock control systems.

h. The adequacy of electronic detection and alarm systems, if any.

i. The adequacy of supervision over employees having access to controlled substances, to storage areas, or to manufacturing areas.

j. The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any.

k. The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel.

l. The availability of local police protection or of the registrant's or applicant's security personnel.

m. The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances.

10.13(3) *Manufacturing and compounding storage areas.* Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in any schedule shall be stored pursuant to federal laws and regulations.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.14(124) Accountability of controlled substances. The registrant shall maintain ultimate accountability of controlled substances and records maintained at the registered location.

10.14(1) *Records.* Pursuant to rule 657—10.36(124,155A), records shall be available for inspection and copying by the board or its authorized agents for two years from the date of the record.

10.14(2) *Policies and procedures.* The registrant shall have policies and procedures that identify, at a minimum:

a. Adequate storage for all controlled substances to ensure security and proper conditions with respect to temperature and humidity.

b. Access to controlled substances and records of controlled substances by employees of the registrant.

c. Proper disposition of controlled substances.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.15 Reserved.

657—10.16(124) Receipt and disbursement of controlled substances. Each transfer of a controlled substance between two registrants, to include a transfer between two separately registered locations regardless of any common ownership, except as provided in subrule 10.16(2), shall require a record of the transaction. Each registrant shall maintain a copy of the record for at least two years from the date of the transfer. Records of the transfer of Schedule II controlled substances shall be created and maintained separately from records of the transfer of Schedules III through V controlled substances pursuant to rule 657—10.36(124,155A). Upon receipt of a controlled substance, the individual responsible for receiving the controlled substance shall date and sign the receipt record.

10.16(1) *Record.* The record, unless otherwise provided in these rules or pursuant to federal law, shall include the following:

a. The name of the substance.

b. The strength and dosage form of the substance.

c. The number of units or commercial containers acquired from other registrants, including the date of receipt and the name, address, and DEA registration number of the registrant from which the substances were acquired.

d. The number of units or commercial containers distributed to other registrants, including the date of distribution and the name, address, and DEA registration number of the registrant to which the substances were distributed.

e. The number of units or commercial containers disposed of in any other manner, including the date and manner of disposal and the name, address, and DEA registration number of the registrant to which the substances were distributed for disposal, if appropriate.

10.16(2) *Distribution of samples and other complimentary packages.* Complimentary packages and samples of controlled substances may be distributed to practitioners pursuant to federal and state law only if the person distributing the items provides to the practitioner a record that contains the information found in this subrule. The individual responsible for receiving the controlled substances shall sign and date the record.

a. The name, address, and DEA registration number of the supplier.

b. The name, address, and DEA registration number of the practitioner.

c. The name, strength, dosage form, and quantity of the specific controlled substances delivered.

d. The date of delivery.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.17(124) Ordering or distributing Schedule I or II controlled substances.

10.17(1) *DEA Form 222.* Except as otherwise provided by subrule 10.17(2) and under federal law, a DEA Form 222 is required for each distribution of a Schedule I or II controlled substance. An order form may be executed only on behalf of the registrant named on the order form and only if the registrant's DEA and Iowa registrations for the substances being purchased have not expired or been revoked or suspended by the issuing agency.

a. Order forms shall be obtained, executed, and filled pursuant to DEA requirements. Each form shall be complete, legible, and properly prepared, executed, and endorsed and shall contain no alteration, erasure, or change of any kind.

b. The purchaser shall submit Copy 1 and Copy 2 of the order form to the supplier.

c. The purchaser shall maintain Copy 3 of the order form in the files of the registrant. Upon receipt of the substances from the supplier, the purchaser shall record on Copy 3 of the order form the quantity of each substance received and the date of receipt.

d. The supplier shall record on Copy 1 and Copy 2 of the order form the quantity of each substance distributed to the purchaser and the date on which the shipment is made. The supplier shall maintain Copy 1 of the order form in the files of the supplier and shall forward Copy 2 of the order form to the DEA district office.

e. Order forms shall be maintained separately from all other records of the registrant.

f. Each unaccepted, defective, or otherwise void order form and any attached statement or other documents relating to any order form shall be maintained in the files of the registrant.

g. If the registration of any purchaser of Schedule I or II controlled substances is terminated for any reason, or if the name or address of the registrant as shown on the registration is changed, the registrant shall return all unused order forms to the DEA district office.

10.17(2) *Electronic ordering system.* A registrant authorized to order or distribute Schedule I or II controlled substances via the DEA Controlled Substances Ordering System (CSOS) shall comply with the requirements of the DEA relating to that system, including the maintenance and security of digital certificates, signatures, and passwords and all record-keeping and reporting requirements.

a. For an electronic order to be valid, the purchaser shall sign the electronic order with a digital signature issued to the purchaser or the purchaser's agent by the DEA.

b. An electronic order may include controlled substances that are not in Schedule I or II and may also include noncontrolled substances.

c. A purchaser shall submit an order to a specific wholesale distributor appropriately licensed to distribute in Iowa.

d. Prior to filling an order, a supplier shall verify the integrity of the signature and the order, verify that the digital certificate has not expired, check the validity of the certificate, and verify the registrant's authority to order the controlled substances.

e. The supplier shall retain an electronic record of every order, including a record of the number of commercial or bulk containers furnished for each item and the date on which the supplier shipped the containers to the purchaser. The shipping record shall be linked to the electronic record of the order. Unless otherwise provided under federal law, a supplier shall ship the controlled substances to the registered location associated with the digital certificate used to sign the order.

f. If an order cannot be filled for any reason, the supplier shall notify the purchaser and provide a statement as to the reason the order cannot be filled. When a purchaser receives such a statement from a supplier, the purchaser shall electronically link the statement of nonacceptance to the original electronic order. Neither a purchaser nor a supplier may correct a defective order; the purchaser must issue a new order for the order to be filled.

g. When a purchaser receives a shipment, the purchaser shall create a record of the quantity of each item received and the date received. The record shall be electronically linked to the original order and shall identify the individual reconciling the order. A purchaser shall, for each order filled, retain the original signed order and all linked records for that order for two years. The purchaser shall also retain all copies of each unfilled or defective order and each linked statement.

h. A supplier shall retain each original order filled and all linked records for two years. A supplier shall, for each electronic order filled, forward to the DEA within two business days either a copy of the electronic order or an electronic report of the order in a format specified by the DEA.

i. Records of CSOS electronic orders and all linked records shall be maintained by a supplier and a purchaser for two years following the date of shipment or receipt, respectively. Records may be maintained electronically or in hard-copy format. Records that are maintained electronically shall be readily retrievable from all other records, shall be easily readable or easily rendered into a readable format, shall be readily retrievable at the registered location, and shall be made available to the board, to the board's agents, or to the DEA upon request. Records maintained in hard-copy format shall be maintained in the same manner as DEA Form 222.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.18(124) Schedule II perpetual inventory. Each registrant located in Iowa that maintains Schedule II controlled substances shall maintain a perpetual inventory system for all Schedule II controlled substances pursuant to this rule. All records relating to the perpetual inventory shall be maintained at the registered location and shall be available for inspection and copying by the board or its representative for a period of two years from the date of the record.

10.18(1) *Record format.* The perpetual inventory record may be maintained in a manual or an electronic record format. Any electronic record shall provide for hard-copy printout of all transactions recorded in the perpetual inventory record for any specified period of time and shall state the current inventory quantities of each drug at the time the record is printed.

10.18(2) *Information included.* The perpetual inventory record shall identify all receipts for and disbursements of Schedule II controlled substances by drug or by national drug code (NDC) number. The record shall be updated to identify each receipt, disbursement, and current balance of each individual drug or NDC number. The record shall also include incident reports and reconciliation records pursuant to subrules 10.18(3) and 10.18(4).

10.18(3) *Changes to a record.* If a perpetual inventory record is able to be changed, the individual making a change to the record shall complete an incident report documenting the change. The incident report shall identify the specific information that was changed including the information before and after the change, shall identify the individual making the change, and shall include the date and the reason the record was changed. If the electronic record system documents within the perpetual inventory record all of the information that must be included in an incident report, a separate report is not required.

10.18(4) *Reconciliation.* The registrant shall be responsible for reconciling or ensuring the completion of a reconciliation of the perpetual inventory balance with the physical inventory of all Schedule II controlled substances at least annually. In case of any discrepancies between the physical inventory and the perpetual inventory, the registrant shall be notified immediately. The registrant shall determine the need for further investigation, and significant discrepancies shall be reported to the board pursuant to rule 657—10.21(124) and to the DEA pursuant to federal DEA regulations. Periodic reconciliation records shall be maintained and available for review and copying by the board or its authorized agents for a period of two years from the date of the record. The reconciliation process may be completed using either of the following procedures or a combination thereof:

a. The individual responsible for a disbursement verifies that the physical inventory matches the perpetual inventory following each disbursement and documents that reconciliation in the perpetual inventory record. If controlled substances are maintained on the patient care unit, the nurse or other responsible licensed health care provider verifies that the physical inventory matches the perpetual inventory following each dispensing and documents that reconciliation in the perpetual inventory record. If any Schedule II controlled substances in the registrant's current inventory have been disbursed and verified in this manner within the year and there are no discrepancies noted, no additional reconciliation action is required. A perpetual inventory record for a drug that has had no activity within the year shall be reconciled pursuant to paragraph 10.18(4)*"b."*

b. A physical count of each Schedule II controlled substance stocked by the registrant shall be completed at least once each year, and that count shall be reconciled with the perpetual inventory record balance. The physical count and reconciliation may be completed over a period of time not to exceed one year in a manner that ensures that the perpetual inventory and the physical inventory of Schedule II controlled substances are annually reconciled. The individual performing the reconciliation shall record the date, the time, the individual's initials or unique identification, and any discrepancies between the physical inventory and the perpetual inventory.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.19(124) Physical count and record of inventory. Each registrant shall be responsible for taking a complete and accurate inventory of all stocks of controlled substances under the control of the registrant pursuant to this rule. The responsible individual may delegate the actual taking of any inventory.

10.19(1) *Record and procedure.* Each inventory record, except the periodic count and reconciliation required pursuant to subrule 10.18(4), shall comply with the requirements of this subrule and shall be maintained for a minimum of two years from the date of the inventory.

a. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date and at the time the inventory is taken.

b. Each inventory shall be maintained in a handwritten, typewritten, or electronically printed form at the registered location. An inventory of Schedule II controlled substances shall be maintained separately from an inventory of all other controlled substances.

c. Controlled substances shall be deemed to be on hand if they are in the possession of or under the control of the registrant. Controlled substances on hand shall include prescriptions prepared for

dispensing to a patient but not yet delivered to the patient, substances maintained in emergency medical service programs, care facility or hospice emergency supplies, outdated or adulterated substances pending destruction, and substances stored in a warehouse on behalf of the registrant. Controlled substances obtained through an authorized collection program for the purpose of disposal shall not be examined, inspected, counted, sorted, inventoried, or otherwise handled.

d. A separate inventory shall be made for each registered location and for each independent activity registered except as otherwise provided under federal law.

e. The inventory shall be taken either prior to opening or following the close of business on the inventory date, and the inventory record shall identify either opening or close of business.

f. The inventory record, unless otherwise provided under federal law, shall include the following information:

(1) The name of the substance.

(2) The strength and dosage form of the substance.

(3) The quantity of the substance.

(4) Information required of authorized collection programs pursuant to federal regulations for such collection programs.

(5) The signature of the person or persons responsible for taking the inventory.

(6) The date and time (opening or closing) of the inventory.

g. For all substances listed in Schedule I or II, the quantity shall be an exact count or measure of the substance.

h. For all substances listed in Schedule III, IV, or V, the quantity may be an estimated count or measure of the substance unless the container has been opened and originally held more than 100 dosage units. If the opened commercial container originally held more than 100 dosage units, an exact count of the contents shall be made. Products packaged in nonincremented containers may be estimated to the nearest one-fourth container.

10.19(2) *Initial inventory.* A new registrant shall take an inventory of all stocks of controlled substances on hand on the date the new registrant first engages in the manufacture, distribution, storage, or dispensing of controlled substances. If the registrant commences business or the registered activity with no controlled substances on hand, the initial inventory shall record that fact.

10.19(3) *Annual inventory.* After the initial inventory is taken, a registrant shall take a new inventory of all stocks of controlled substances on hand at least annually. The annual inventory may be taken on any date that is within 372 days after the date of the previous annual inventory.

10.19(4) *Change of ownership, pharmacist in charge, or registered location.* When there is a change in ownership, pharmacist in charge, or location for a registration, an inventory shall be taken of all controlled substances in compliance with subrule 10.19(1). The inventory shall be taken following the close of business the last day under terminating ownership, terminating pharmacist in charge's employment, or at the location being vacated. The inventory shall serve as the ending inventory for the terminating owner, terminating pharmacist in charge, or location being vacated, as well as a record of the beginning inventory for the new owner, pharmacist in charge, or location.

10.19(5) *Discontinuing registered activity.* A registrant shall take an inventory of controlled substances at the close of business the last day the registrant is engaged in registered activities. If the registrant is selling or transferring the remaining controlled substances to another registrant, this inventory shall serve as the ending inventory for the registrant discontinuing business as well as a record of additional or starting inventory for the registrant to which the substances are transferred.

10.19(6) *New or rescheduled controlled substances.* On the effective date of the addition of a previously noncontrolled substance to any schedule of controlled substances or the rescheduling of a previously controlled substance to another schedule, any registrant who possesses the newly scheduled or rescheduled controlled substance shall take an inventory of all stocks of the substance on hand. That inventory record shall be maintained with the most recent controlled substances inventory record. Thereafter, the controlled substance shall be included in the appropriate schedule of each inventory made by the registrant.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.20 Reserved.

657—10.21(124) Report of theft or loss. A registrant shall report to the board and the DEA any theft or significant loss of controlled substances when the loss is attributable to other than inadvertent error. Thefts or other losses of controlled substances shall be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them.

10.21(1) *Immediate notice to board.* If the theft was committed by a registrant or licensee of the board, or if there is reason to believe that the theft was committed by a registrant or licensee of the board, the registrant from which the controlled substances were stolen shall notify the board immediately upon discovery of the theft and shall identify to the board the registrant or licensee suspected of the theft.

10.21(2) *Immediate notice to DEA.* A registrant shall deliver notice, immediately upon discovery of a reportable theft or loss of controlled substances, to the Des Moines DEA field office via telephone, facsimile, or a brief written message explaining the circumstances of the theft or loss.

10.21(3) *Timely report submission.* Within 14 calendar days of discovery of the theft or loss, a registrant shall submit directly to the DEA a Form 106 or alternate required form via the DEA website at www.deadiversion.usdoj.gov/. A copy of the report that was completed and submitted to the DEA shall be immediately submitted to the board via facsimile, email attachment, or personal or commercial delivery.

10.21(4) *Record maintained.* A copy of the report shall be maintained in the registrant's files for a minimum of two years following the date the report was completed.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.22(124) Disposal of registrant stock. A registrant shall dispose of controlled substances pursuant to the requirements of this rule. Disposal records shall be maintained by the registrant for at least two years from the date of the record.

10.22(1) *Registrant stock supply.* Controlled substances shall be removed from current inventory and disposed of by one of the following procedures.

a. The registrant shall utilize the services of a DEA-registered and Iowa-licensed reverse distributor.

b. The board may authorize and instruct the registrant to dispose of the controlled substances in one of the following manners:

(1) By delivery to an agent of the board or to the board office.

(2) By destruction of the drugs in the presence of a board officer, agent, inspector, or other authorized individual.

(3) By such other means as the board may determine to ensure that drugs do not become available to unauthorized persons.

10.22(2) *Waste resulting from administration or compounding.* Except as otherwise specifically provided by federal or state law or rules of the board, the unused portion of a controlled substance resulting from administration to a patient from a registrant's stock or emergency supply or resulting from drug compounding operations may be destroyed or otherwise disposed of by the registrant or a pharmacist in witness of one other licensed health care provider or a registered pharmacy technician 18 years of age or older pursuant to this subrule. A written record of the wastage shall be made and maintained by the registrant for a minimum of two years following the wastage. The record shall include the following:

a. The controlled substance wasted.

b. The date of wastage.

c. The quantity or estimated quantity of the wasted controlled substance.

d. The source of the controlled substance, including identification of the patient to whom the substance was administered or the drug compounding process utilizing the controlled substance.

e. The reason for the waste.

f. The signatures of both individuals involved in the wastage.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.23(124) Disposal of previously dispensed controlled substances. Except as provided in 657—Chapter 23 for care facilities, a registrant may not dispose of previously dispensed controlled substances unless the registrant has modified its registration with DEA to administer an authorized collection program. A registrant shall not take possession of a previously dispensed controlled substance except for reuse for the same patient.
[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.24(124,126,155A) Prescription requirements. All prescriptions for controlled substances shall be dated as of, and signed on, the day issued. Controlled substances prescriptions shall be valid for six months following date of issue. A prescription for a Schedule III, IV, or V controlled substance may include authorization to refill the prescription no more than five times within the six months following date of issue. A prescription for a Schedule II controlled substance shall not be refilled.

10.24(1) *Form of prescription.* All prescriptions for controlled substances shall bear the full name and address of the patient; the drug name, strength, dosage form, quantity prescribed, and directions for use; and the name, address, and DEA registration number of the prescriber. All prescriptions for controlled substances issued by individual prescribers shall include the legibly preprinted, typed, or hand-printed name of the prescriber as well as the prescriber's written or electronic signature.

a. When an oral order is not permitted, or when a prescriber is unable to prepare and transmit an electronic prescription in compliance with DEA requirements for electronic prescriptions, prescriptions shall be written with ink, indelible pencil, or typed print and shall be manually signed by the prescriber. If the prescriber utilizes an electronic prescription application that meets DEA requirements for electronic prescriptions, the prescriber may electronically prepare and transmit a prescription for a controlled substance to a pharmacy that utilizes a pharmacy prescription application that meets DEA requirements for electronic prescriptions.

b. A prescriber's agent may prepare a prescription for the review, authorization, and manual or electronic signature of the prescriber, but the prescribing practitioner is responsible for the accuracy, completeness, and validity of the prescription.

c. An electronic prescription for a controlled substance shall not be transmitted to a pharmacy except by the prescriber in compliance with DEA regulations.

d. A prescriber shall securely maintain the unique authentication credentials issued to the prescriber for utilization of the electronic prescription application and authentication of the prescriber's electronic signature. Unique authentication credentials issued to any individual shall not be shared with or disclosed to any other prescriber, agent, or individual.

e. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by this rule.

10.24(2) *Verification by pharmacist.* The pharmacist shall verify the authenticity of the prescription with the individual prescriber or the prescriber's agent in each case when a written or oral prescription for a Schedule II controlled substance is presented for filling and neither the prescribing individual practitioner issuing the prescription nor the patient or patient's agent is known to the pharmacist. The pharmacist shall verify the authenticity of the prescription with the individual prescriber or the prescriber's agent in any case when the pharmacist questions the validity of, including the legitimate medical purpose for, the prescription. The pharmacist is required to record the manner by which the prescription was verified and include the pharmacist's name or unique identifier.

10.24(3) *Intern, resident, foreign physician.* An intern, resident, or foreign physician exempt from registration pursuant to subrule 10.8(5) shall include on all prescriptions issued the hospital's registration number and the special internal code number assigned by the hospital in lieu of the prescriber's registration number required by this rule. Each prescription shall include the stamped or legibly printed name of the prescribing intern, resident, or foreign physician as well as the prescriber's signature.

10.24(4) *Valid prescriber/patient relationship.* Once the prescriber/patient relationship is broken and the prescriber is no longer available to treat the patient or to oversee the patient's use of the controlled substance, a prescription shall lose its validity. A prescriber/patient relationship shall be deemed broken

when the prescriber dies, retires, or moves out of the local service area or when the prescriber's authority to prescribe is suspended, revoked, or otherwise modified to exclude authority for the schedule in which the prescribed substance is listed. The pharmacist, upon becoming aware of the situation, shall cancel the prescription and any remaining refills. However, the pharmacist shall exercise prudent judgment based upon individual circumstances to ensure that the patient is able to obtain a sufficient amount of the drug to continue treatment until the patient can reasonably obtain the service of another prescriber and a new prescription can be issued.

10.24(5) *Facsimile transmission of a controlled substance prescription.* With the exception of an authorization for emergency dispensing as provided in rule 657—10.26(124), a prescription for a controlled substance in Schedules II, III, IV and V may be transmitted via facsimile from a prescriber to a pharmacy only as provided in rule 657—21.9(124,155A).

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.25(124) Dispensing records. Each registrant shall create a record of controlled substances dispensed to a patient or research subject.

10.25(1) *Record maintained and available.* The record shall be maintained for two years from the date of dispensing and be available for inspection and copying by the board or its authorized agents.

10.25(2) *Record contents.* The record shall include the following information:

a. The name and address of the person to whom dispensed.

b. The date of dispensing.

c. The name or NDC number, strength, dosage form, and quantity of the substance dispensed.

d. The name of the prescriber, unless dispensed by the prescriber.

e. The unique identification of each technician, pharmacist, pharmacist-intern, prescriber, or prescriber's agent involved in dispensing.

f. The serial number or unique identification number of the prescription.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.26(124) Schedule II emergency prescriptions.

10.26(1) *Emergency situation defined.* For the purposes of authorizing an oral or facsimile transmission of a prescription for a Schedule II controlled substance listed in Iowa Code section 124.206, the term "emergency situation" means those situations in which the prescribing practitioner determines that all of the following apply:

a. Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user.

b. No appropriate alternative treatment is available, including administration of a drug that is not a Schedule II controlled substance.

c. It is not reasonably possible for the prescribing practitioner to provide a manually signed written prescription to be presented to the pharmacy before the pharmacy dispenses the controlled substance, or the prescribing practitioner is unable to provide a DEA-compliant electronic prescription to the pharmacy before the pharmacy dispenses the controlled substance.

10.26(2) *Requirements of emergency prescription.* In the case of an emergency situation as defined in subrule 10.26(1), a pharmacist may dispense a controlled substance listed in Schedule II pursuant to a facsimile transmission or upon receiving oral authorization of a prescribing individual practitioner provided that:

a. The quantity prescribed and dispensed is limited to the smallest available quantity to meet the needs of the patient during the emergency period. Dispensing beyond the emergency period requires a written prescription manually signed by the prescribing individual practitioner or a DEA-compliant electronic prescription.

b. If the pharmacist does not know the prescribing individual practitioner, the pharmacist shall make a reasonable effort to determine that the authorization came from an authorized prescriber. The pharmacist shall record the manner by which the authorization was verified and include the pharmacist's name or unique identification.

c. The pharmacist shall prepare a temporary written record of the emergency prescription. The temporary written record shall consist of a hard copy of the facsimile transmission or a written record of the oral transmission authorizing the emergency dispensing. A written record is not required to consist of a handwritten record and may be a printed facsimile or a print of a computer-generated record of the prescription if the printed record includes all of the required elements for the prescription. If the emergency prescription is transmitted by the practitioner's agent, the record shall include the first and last names and title of the individual who transmitted the prescription.

d. If the emergency prescription is transmitted via facsimile transmission, the means of transmission shall not obscure or render the prescription information illegible due to security features of the paper utilized by the prescriber to prepare the written prescription, and the hard-copy record of the facsimile transmission shall not be obscured or rendered illegible due to such security features.

e. Within seven days after authorizing an emergency prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of rule 657—10.24(124,126,155A), the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the emergency order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the seven-day period. The written prescription shall be attached to and maintained with the temporary written record prepared pursuant to paragraph 10.26(2)*"c."*

f. The pharmacist shall notify the board and the DEA if the prescribing individual fails to deliver a written prescription. Failure of the pharmacist to so notify the board and the DEA, or failure of the prescribing individual to deliver the required written prescription as herein required, shall void the authority conferred by this subrule.

g. Pursuant to federal law and subrule 10.27(3), the pharmacist may fill a partial quantity of an emergency prescription so long as the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed and that the remaining portions are filled no later than 72 hours after the prescription is issued.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.27(124) Schedule II prescriptions—partial filling. The partial filling of a prescription for a controlled substance listed in Schedule II is permitted as provided in this rule and federal regulations.

10.27(1) *Insufficient supply on hand.* If the pharmacist is unable to supply the full quantity authorized in a prescription and makes a notation of the quantity supplied on the prescription record, a partial fill of the prescription is permitted. The remaining portion of the prescription must be filled within 72 hours of the first partial filling. If the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescriber. No further quantity may be supplied beyond 72 hours without a new prescription.

10.27(2) *Long-term care or terminally ill patient.* A prescription for a Schedule II controlled substance written for a patient in a long-term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units as provided by this subrule.

a. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner prior to partially filling the prescription. Both the pharmacist and the practitioner have a corresponding responsibility to ensure that the controlled substance is for a terminally ill patient.

b. The pharmacist shall record on the prescription whether the patient is "terminally ill" or an "LTCF patient." For each partial filling, the dispensing pharmacist shall record on the back of the prescription or on another appropriate uniformly maintained and readily retrievable record, the date of the partial filling, the quantity dispensed, the remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.

c. The total quantity of Schedule II controlled substances dispensed in all partial fillings shall not exceed the total quantity prescribed. Schedule II prescriptions for patients in an LTCF or for patients

with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of the drug.

d. Information pertaining to current Schedule II prescriptions for patients in an LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system pursuant to rule 657—21.4(124,155A).

10.27(3) *Patient or prescriber request.* At the request of the patient or prescriber, a prescription for a Schedule II controlled substance may be partially filled pursuant to this subrule and federal law. The total quantity dispensed in all partial fillings shall not exceed the total quantity prescribed. Except as provided in paragraph 10.26(2)*"g,"* the remaining portion of a prescription partially filled pursuant to this subrule may be filled within 30 days of the date the prescription was issued.
[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.28(124) Schedule II medication order. Schedule II controlled substances may be administered or dispensed to institutionalized patients pursuant to a medication order as provided in 657—subrule 7.13(1) or rule 657—23.9(124,155A), as applicable.
[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—10.29(124) Schedule II—issuing multiple prescriptions. An individual prescriber may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance pursuant to the provisions and limitations of this rule.

10.29(1) *Refills prohibited.* The issuance of refills for a Schedule II controlled substance is prohibited. The use of multiple prescriptions for the dispensing of Schedule II controlled substances, pursuant to this rule, ensures that the prescriptions are treated as separate dispensing authorizations and not as refills of an original prescription.

10.29(2) *Legitimate medical purpose.* Each separate prescription issued pursuant to this rule shall be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of the prescriber's professional practice.

10.29(3) *Dates and instructions.* Each prescription issued pursuant to this rule shall be dated as of and manually signed by the prescriber on the day the prescription is issued. Each separate prescription, other than the first prescription if that prescription is intended to be filled immediately, shall contain written instructions indicating the earliest date on which a pharmacist may fill each prescription.

10.29(4) *Authorized fill date unalterable.* Regardless of the provisions of rule 657—10.30(124), when a prescription contains instructions from the prescriber indicating that the prescription shall not be filled before a certain date, a pharmacist shall not fill the prescription before that date. The pharmacist shall not contact the prescriber for verbal authorization to fill the prescription before the fill date originally indicated by the prescriber pursuant to this rule.

10.29(5) *Number of prescriptions and authorized quantity.* An individual prescriber may issue for a patient as many separate prescriptions, to be filled sequentially pursuant to this rule, as the prescriber deems necessary to provide the patient with adequate medical care. The cumulative effect of the filling of each of these separate prescriptions shall result in the receipt by the patient of a quantity of the Schedule II controlled substance not exceeding a 90-day supply.

10.29(6) *Prescriber's discretion.* Nothing in this rule shall be construed as requiring or encouraging an individual prescriber to issue multiple prescriptions pursuant to this rule or to see the prescriber's patients once every 90 days when prescribing Schedule II controlled substances. An individual prescriber shall determine, based on sound medical judgment and in accordance with established medical standards, how often to see patients and whether it is appropriate to issue multiple prescriptions pursuant to this rule.
[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.30(124) Schedule II—changes to a prescription. With appropriate verification, a pharmacist may add information provided by the patient or patient's agent, such as the patient's address, to a Schedule II controlled substance prescription.

10.30(1) *Changes prohibited.* A pharmacist shall never change the patient's name, the controlled substance prescribed except for generic substitution, or the name or signature of the prescriber.

10.30(2) *Changes authorized.* After consultation with the prescriber or the prescriber's agent and documentation of such consultation, a pharmacist may change or add the following information on a Schedule II controlled substance prescription:

a. The drug strength.

b. The dosage form.

c. The drug quantity.

d. The directions for use.

e. The date the prescription was issued.

f. The prescriber's address or DEA registration number.

g. The name of the supervising prescriber if the prescription was issued by a physician assistant.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.31 Reserved.

657—10.32(124) Schedule III, IV, or V prescription. No prescription for a controlled substance listed in Schedule III, IV, or V shall be filled or refilled more than six months after the date on which it was issued nor be refilled more than five times.

10.32(1) *Record.* Each filling and refilling of a prescription shall be entered in a uniformly maintained and readily retrievable record in accordance with rule 657—10.25(124). If the pharmacist merely initials or affixes the pharmacist's unique identifier and dates the back of the prescription, it shall be deemed that the full face amount of the prescription has been dispensed.

10.32(2) *Oral refill authorization.* The prescribing practitioner may authorize additional refills of Schedule III, IV, or V controlled substances on the original prescription through an oral refill authorization transmitted to an authorized individual at the pharmacy provided the following conditions are met:

a. The total quantity authorized, including the amount of the original prescription, does not exceed five refills nor extend beyond six months from the date of issuance of the original prescription.

b. The pharmacist, pharmacist-intern, or technician who obtains the oral authorization from the prescriber who issued the original prescription documents, on or with the original prescription, the date authorized, the quantity of each refill, the number of additional refills authorized, and the unique identification of the authorized individual.

c. The quantity of each additional refill is equal to or less than the quantity authorized for the initial filling of the original prescription.

d. The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five-refill, six-month limitation.

10.32(3) *Partial fills.* The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that each partial fill is recorded in the same manner as a refill pursuant to subrule 10.32(1). The total quantity dispensed in all partial fills shall not exceed the total quantity prescribed.

10.32(4) *Medication order.* A Schedule III, IV, or V controlled substance may be administered or dispensed to institutionalized patients pursuant to a medication order as provided in 657—subrule 7.13(1) or rule 657—23.9(124,155A), as applicable.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.33(124,155A) Dispensing Schedule V controlled substances without a prescription. A controlled substance listed in Schedule V, which substance is not a prescription drug as determined under the federal Food, Drug, and Cosmetic Act, and excepting products containing ephedrine, pseudoephedrine, or phenylpropanolamine, may be dispensed or administered without a prescription by a pharmacist to a purchaser at retail pursuant to the conditions of this rule.

10.33(1) *Who may dispense.* Dispensing shall be by a licensed Iowa pharmacist or by a registered pharmacist-intern under the direct supervision of a pharmacist preceptor. This subrule does not prohibit,

after the pharmacist has fulfilled the professional and legal responsibilities set forth in this rule and has authorized the dispensing of the substance, the completion of the actual cash or credit transaction or the delivery of the substance by a nonpharmacist.

10.33(2) *Frequency and quantity.* Dispensing at retail to the same purchaser in any 48-hour period shall be limited to no more than one of the following quantities of a Schedule V controlled substance:

a. 240 cc (8 ounces) of any controlled substance containing opium.

b. 120 cc (4 ounces) of any other controlled substance.

c. 48 dosage units of any controlled substance containing opium.

d. 24 dosage units of any other controlled substance.

10.33(3) *Age of purchaser.* The purchaser shall be at least 18 years of age.

10.33(4) *Identification.* The pharmacist shall require every purchaser under this rule who is not known by the pharmacist to present a government-issued photo identification, including proof of age when appropriate.

10.33(5) *Record.* A bound record book (i.e., with pages sewn or glued to the spine) for dispensing of Schedule V controlled substances pursuant to this rule shall be maintained by the pharmacist. The book shall contain the name and address of each purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or unique identification of the pharmacist or pharmacist-intern who approved the dispensing of the substance to the purchaser.

10.33(6) *Prescription not required under other laws.* No other federal or state law or regulation requires a prescription prior to distributing or dispensing the Schedule V controlled substance.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.34(124) Dispensing products containing ephedrine, pseudoephedrine, or phenylpropanolamine without a prescription. A product containing ephedrine, pseudoephedrine, or phenylpropanolamine, which substance is a Schedule V controlled substance and is not listed in another controlled substance schedule, may be dispensed or administered without a prescription by a pharmacist, pharmacist-intern, or certified pharmacy technician to a purchaser at retail pursuant to the conditions of this rule.

10.34(1) *Who may dispense.* Dispensing shall be by a licensed Iowa pharmacist, by a registered pharmacist-intern under the direct supervision of a pharmacist preceptor, or by a registered certified pharmacy technician under the direct supervision of a pharmacist, except as authorized in 657—Chapter 100. This subrule does not prohibit, after the pharmacist, pharmacist-intern, or certified pharmacy technician has fulfilled the professional and legal responsibilities set forth in this rule and has authorized the dispensing of the substance, the completion of the actual cash or credit transaction or the delivery of the substance by another pharmacy employee.

10.34(2) *Packaging of nonliquid forms.* A nonliquid form of a product containing ephedrine, pseudoephedrine, or phenylpropanolamine includes gel caps. Nonliquid forms of these products to be sold pursuant to this rule shall be packaged either in blister packaging with each blister containing no more than two dosage units or, if blister packs are technically infeasible, in unit dose packets or pouches.

10.34(3) *Frequency and quantity.* Dispensing without a prescription to the same purchaser within any 30-day period shall be limited to products collectively containing no more than 7,500 mg of ephedrine, pseudoephedrine, or phenylpropanolamine; dispensing without a prescription to the same purchaser within a single calendar day shall not exceed 3,600 mg.

10.34(4) *Age of purchaser.* The purchaser shall be at least 18 years of age.

10.34(5) *Identification.* The pharmacist, pharmacist-intern, or certified pharmacy technician shall require every purchaser under this rule to present a current government-issued photo identification, including proof of age when appropriate. The pharmacist, pharmacist-intern, or certified pharmacy technician shall be responsible for verifying that the name on the identification matches the name provided by the purchaser and that the photo image depicts the purchaser.

10.34(6) *Record.* Purchase records shall be recorded in the real-time electronic pseudoephedrine tracking system (PTS) established and administered by the governor's office of drug control policy

pursuant to 657—Chapter 100. If the PTS is unavailable for use, the purchase record shall be recorded in an alternate format and submitted to the PTS as provided in 657—subrule 100.3(4).

a. Alternate record contents. The alternate record shall contain the following:

(1) The name, address, and signature of the purchaser.

(2) The name and quantity of the product purchased, including the total milligrams of ephedrine, pseudoephedrine, or phenylpropanolamine contained in the product.

(3) The date and time of the purchase.

(4) The name or unique identification of the pharmacist, pharmacist-intern, or certified pharmacy technician who approved the dispensing of the product.

b. Alternate record format. The record shall be maintained using one of the following options:

(1) A hard-copy record.

(2) A record in the pharmacy's electronic prescription dispensing record-keeping system that is capable of producing a hard-copy printout of a record.

(3) A record in an electronic data collection system that captures each of the data elements required by this subrule and that is capable of producing a hard-copy printout of a record.

c. PTS records retrieval. Pursuant to 657—subrule 100.4(6), the pharmacy shall be able to produce a hard-copy printout of transactions recorded in the PTS by the pharmacy for one or more specific products for a specified period of time upon request by the board or its representative or to such other persons or governmental agencies authorized by law to receive such information.

10.34(7) *Notice required.* The pharmacy shall ensure that the following notice is provided to purchasers of ephedrine, pseudoephedrine, or phenylpropanolamine products and that the notice is displayed with or on the electronic signature device or is displayed in the dispensing area and visible to the public:

"Warning: Section 1001 of Title 18, United States Code, states that whoever, with respect to the logbook, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any materially false, fictitious, or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, shall be fined not more than $250,000 if an individual or $500,000 if an organization, imprisoned not more than five years, or both."

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.35 Reserved.

657—10.36(124,155A) Records. Every record required to be kept under this chapter or under Iowa Code chapter 124 shall be kept by the registrant and be available for inspection and copying by the board or its representative for at least two years from the date of such record except as otherwise required in these rules. Controlled substances records shall be maintained in a readily retrievable manner that establishes the receipt and distribution of all controlled substances. Original records more than 12 months old may be maintained in a secure remote storage area unless such remote storage is prohibited under federal law. If the secure storage area is not located within the same physical structure as the registrant, the records must be retrievable within 48 hours of a request by the board or its authorized agent.

10.36(1) *Schedule I and II records.* Records of controlled substances listed in Schedules I and II shall be maintained separately from all other records of the registrant.

10.36(2) *Schedule III, IV, and V records.* Records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the required information is readily retrievable from the ordinary business records of the registrant.

10.36(3) *Date of record.* The date on which a controlled substance is actually received, imported, distributed, exported, disposed of, or otherwise transferred shall be used as the date of receipt, importation, distribution, exportation, disposal, or transfer.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.37 Reserved.

657—10.38(124) Revision of controlled substances schedules.

10.38(1) *Designation of new controlled substance.* The board may designate any new substance as a controlled substance to be included in any of the schedules in Iowa Code chapter 124 no sooner than 30 days following publication in the Federal Register of a final order so designating the substance under federal law. Designation of a new controlled substance under this subrule shall be temporary as provided in Iowa Code section 124.201(4).

10.38(2) *Objection to designation of a new controlled substance.* The board may object to the designation of any new substance as a controlled substance within 30 days following publication in the Federal Register of a final order so designating the substance under federal law. The board shall file objection to the designation of a substance as controlled, shall afford all interested parties an opportunity to be heard, and shall issue the board's decision on the new designation as provided in Iowa Code section 124.201(4).

10.38(3) *Cannabidiol investigational product.* If a cannabidiol investigational product approved as a prescription drug medication by the United States Food and Drug Administration is eliminated from or revised in the federal schedule of controlled substances by the DEA and notice of the elimination or revision is given to the board, the board shall similarly eliminate or revise the prescription drug medication in the schedule of controlled substances. Such action by the board shall be immediately effective upon the date of publication of the final regulation containing the elimination or revision in the Federal Register.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 3743C**, IAB 4/11/18, effective 5/16/18]

657—10.39(124) Temporary designation of controlled substances.

10.39(1) Amend Iowa Code section 124.206(7) by adding the following new paragraph *"c"*:

c. Dronabinol [(-)-delta-9-trans-tetrahydrocannabinol] in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration.

10.39(2) Amend Iowa Code section 124.204(9) by adding the following new paragraphs:

t. Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: 5F-ADB; 5F-MDMB-PINACA.

u. Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers. Other name: 5F-AMB.

v. N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: 5F-APINACA, 5F-AKB48.

w. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers. Other name: ADB-FUBINACA.

x. Methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: MDMB-CHMICA, MMB-CHMINACA.

y. Methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers. Other name: MDMB-FUBINACA.

z. N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other names: 4-fluoroisobutyryl fentanyl, para-fluoroisobutyryl fentanyl.

aa. N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide. Other names: ortho-fluorofentanyl or 2-fluorofentanyl.

ab. N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide. Other name: tetrahydrofuranyl fentanyl.

ac. 2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide. Other name: methoxyacetyl fentanyl.

ad. N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide. Other names: acryl fentanyl or acryloylfentanyl.

ae. Methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: FUB-AMB, MMB-FUBINACA, AMB-FUBINACA.

af. N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide, its isomers, esters, ethers, salts and salts of isomers, esters, and ethers. Other name: cyclopropyl fentanyl.

ag. N-(1-phenethylpiperidin-4-yl)-N-phenylpentanamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other name: valeryl fentanyl.

ah. N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other name: para-fluorobutyryl fentanyl.

ai. N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)butyramide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other name: para-methoxybutyryl fentanyl.

aj. N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other name: para-chloroisobutyryl fentanyl.

ak. N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other name: isobutyryl fentanyl.

al. N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other name: cyclopentyl fentanyl.

am. N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other name: ocfentanil.

10.39(3) Amend Iowa Code section 124.204(2) by adding the following new paragraph:

be. MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine).

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 3860C**, IAB 6/20/18, effective 7/25/18]

657—10.40(124) Excluded and exempt substances. The Iowa board of pharmacy hereby excludes from all schedules the current list of "Excluded Nonnarcotic Products" identified in Title 21, CFR Part 1308, Section 22, and the list of "Exempted Prescription Products" described in Title 21, CFR Part 1308, Section 32. Copies of such lists may be obtained by written request to the board office at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.41(124) Anabolic steroid defined. Anabolic steroid, as defined in Iowa Code section 126.2(2), includes any substance identified as such in Iowa Code section 124.208(6) or 126.2(2).

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.42(124B) Additional precursor substances. Pursuant to Iowa Code section 124B.2(2), the list of precursor substances identified in Iowa Code section 124B.2(1) is amended by adding the following new paragraph:

ab. Alpha-phenylacetoacetonitrile and its salts, optical isomers, and salts of optical isomers. Other name: APAAN.

[**ARC 3860C**, IAB 6/20/18, effective 7/25/18]

657—10.43(124) Reporting discipline and criminal convictions. A registrant shall provide written notice to the board of any disciplinary or enforcement action imposed by any licensing or regulatory authority on any license or registration held by the registrant no later than 30 days after the final action. Discipline may include, but is not limited to, fine or civil penalty, citation or reprimand, probationary period, suspension, revocation, and voluntary surrender. A registrant shall provide written notice to the board of any criminal conviction of the registrant or of any owner that is related to the operation of the registered location no later than 30 days after the conviction. The term criminal conviction includes instances when the judgment of conviction or sentence is deferred.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.44(124) Discipline. Pursuant to 657—Chapter 36, the board may fine, suspend, revoke, or impose other disciplinary sanctions on a registration for any of the following:

1. Any violation of the federal Food, Drug, and Cosmetic Act or federal regulations promulgated under the Act.

2. Any conviction of a crime related to controlled substances committed by the registrant, or if the registrant is an association, joint stock company, partnership, or corporation, by any managing officer.

3. Refusing access to the registered location or registrant records to an agent of the board for the purpose of conducting an inspection or investigation.

4. Failure to maintain registration pursuant to 657—Chapter 10.

5. Any violation of Iowa Code chapter 124, 124B, 126, 155A, or 205, or any rule of the board, including the disciplinary grounds set forth in 657—Chapter 36.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 3857C**, IAB 6/20/18, effective 7/25/18]

These rules are intended to implement Iowa Code sections 124.201, 124.301 to 124.308, 124.402, 124.403, 124.501, 126.2, 126.11, 147.88, 155A.13, 155A.17, 155A.26, 155A.37, and 205.3.

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CHAPTER 11
DRUGS IN EMERGENCY MEDICAL SERVICE PROGRAMS
[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 11]

657—11.1(124,147A,155A) Definitions. For the purpose of this chapter, the following definitions shall apply:

"Adulterated" means any drug or device that consists in whole or in part of any filthy, putrid, or decomposed substance.

"Ambulance service" means any privately or publicly owned service program that utilizes ambulances, including air transport vehicles, in order to provide patient transportation and emergency medical services.

"Authorized prescriber" means any provider who has prescriptive authority in the state of Iowa.

"Board" means the board of pharmacy.

"Bureau" means the Iowa department of public health, bureau of emergency and trauma services (BETS).

"Controlled substance" means any drug that is identified in Schedules I through V of Iowa Code chapter 124, the Iowa uniform controlled substances Act.

"CSA registration" means a registration issued by the board pursuant to Iowa Code chapter 124, the Iowa uniform controlled substances Act.

"DEA" means the U.S. Department of Justice, Drug Enforcement Administration.

"DEA registration" means a registration issued by the DEA pursuant to 21 CFR Part 1301.

"Department" means the Iowa department of public health.

"Drug" means a substance as defined in Iowa Code section 155A.3(13) but does not include nonmedicated intravenous solutions such as saline.

"Emergency medical care provider" means an emergency medical care provider as defined in 641—131.1(147A).

"Emergency medical services" or *"EMS"* means an integrated medical care delivery system to provide emergency and nonemergency medical care.

"Emergency medical technician" or *"EMT"* means any emergency medical technician or EMT as defined in 641—131.1(147A).

"Medical direction" means direction, advice, or orders provided, in accordance with written parameters and protocols, to emergency medical care personnel by a medical director, supervising physician, or physician designee.

"Medical director" means any physician licensed under Iowa Code chapter 148, 150, or 150A who shall be responsible for overall medical direction of the service program and who has completed a medical director workshop, sponsored by the department, within one year of assuming duties.

"Medical director-based" means that ownership of the drugs maintained in and used by the service program remains with the medical director.

"Patient care report" means a computerized or written report that documents the assessment and management of the patient by the emergency medical care provider.

"Pharmacy-based" means that ownership of the drugs maintained in and used by the service program remains with the pharmacy.

"Physician" means any individual licensed under Iowa Code chapter 148, 150, or 150A.

"Physician assistant" or *"PA"* means any individual licensed under Iowa Code chapter 148C.

"Primary program site" means the physical location from which the service program is operated and at which stock supplies of prescription drugs may be maintained and distributed to a program vehicle and a program substation.

"Program substation" means the physical location from which a service program is operated as a branch or extension of a primary program site, at which an emergency kit or supply of prescription drugs is maintained, and at which a stock supply of prescription drugs is not maintained.

"Protocols" means written direction and orders, consistent with the department's standard of care, that are to be followed by an emergency medical care provider in emergency and nonemergency

situations. Protocols shall be approved by the service program's medical director and shall address the care of both adult and pediatric patients.

"Responsible individual" means the individual who maintains legal responsibility of the prescription drugs and devices. "Responsible individual" includes the medical director in a medical director-based service program or the pharmacist in charge in a pharmacy-based service program.

"Service" or *"service program"* means any medical care ambulance service or nontransport service that has received authorization from the department.

"Service director" means the individual who is responsible for the operation and administration of a service program.

"Supervising physician" means any physician licensed under Iowa Code chapter 148, 150, or 150A who supervises and is responsible for medical direction of emergency medical care personnel when such personnel are providing emergency medical care.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 0342C**, IAB 10/3/12, effective 11/7/12; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.2(124,147A,155A) Responsibility. Each service program shall appoint a service director at the primary program site and shall have a responsible individual who is responsible for ensuring that the management of all prescription drugs complies with federal and state laws and regulations. In service programs that maintain both a pharmacy-based service program agreement and a medical director-based service program agreement, the responsible individual for each service program agreement shall be responsible for ensuring the management of drugs under that individual's ownership. If more than one pharmacy enters into an agreement with a pharmacy-based service program, the pharmacist in charge at each pharmacy is responsible for the rules and laws pertaining to the specific prescription drugs, including controlled substances, that each pharmacy provides to the service program.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.3(124,147A,155A) Registration required. In any service program which intends to provide services in or into Iowa that include the administration of controlled substances, the responsible individual shall ensure that each primary program site, regardless of location, is registered with the board pursuant to this rule. The current registration certificate shall be available at the primary program site for inspection and copying by the board, its representative, or any other authorized individual.

11.3(1) *Medical director-based service program.* In a medical director-based service program, CSA and DEA registrations shall be obtained for each primary program site in the name of the medical director. CSA and DEA registrations shall be obtained prior to procurement of any controlled substances for use in the service program. Separate registrations for program substations shall not be required. In a medical director-based service program, a CSA registration shall also be obtained in the name of the service program, shall secondarily name the medical director, and shall be issued for the address of the service program's primary program site.

11.3(2) *Pharmacy-based service program.* In a pharmacy-based service program, the CSA registration shall be issued in the name of the service program and shall secondarily name the provider pharmacy. The CSA registration shall be issued for the address of the service program's primary program site and shall identify the pharmacist in charge of the provider pharmacy as the individual responsible for the controlled substances at the service program. A pharmacy-based service program that is owned by and physically located at the same address as an Iowa-licensed and -registered hospital may, but is not required to, obtain a separate registration.

11.3(3) *Combination pharmacy-based and medical director-based service program.* In a service program that is a combination of pharmacy-based and medical director-based and both the pharmacy and medical director provide controlled substances, each provider of controlled substances shall maintain a CSA registration with the board as provided by this rule. A medical director-based program shall also maintain a federal DEA registration as provided by this rule.

11.3(4) *Change of address of registered primary program site.* A registrant shall apply to change the address of the registered primary program site by submitting a completed application and fee as provided in 657—subrule 10.9(2).

11.3(5) *Discontinuation of medical director in a medical director-based service program.* If a medical director intends to terminate a written agreement with a service program pursuant to rule 657—11.5(124,147A,155A), the medical director shall provide written notification to the board at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309, pursuant to 657—subrule 10.11(6), to cancel the registration, including the effective date of the termination of the agreement. The registration certificate shall be returned to the board no later than ten days following the effective date of the termination of the agreement.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17; **ARC 3637C**, IAB 2/14/18, effective 3/21/18; **ARC 3861C**, IAB 6/20/18, effective 7/25/18]

657—11.4(124,147A,155A) Written agreement. A signed, written agreement for the service program shall be maintained at the primary program site and be available for inspection and copying by the board, its representative, or any other authorized individual.

11.4(1) *Pharmacy-based service programs.* An Iowa-licensed pharmacy may enter into an agreement with a service program located in the state. The agreement with the service program shall establish that the service program is operating as an extension of the pharmacy with respect to the prescription drugs the pharmacy provides to the service program. The agreement shall be signed by the pharmacist in charge and the service director at the primary program site. A copy of this agreement shall be maintained at both the pharmacy and the primary program site while the agreement is in effect. Nothing in this rule prohibits more than one pharmacy from entering into an agreement with a service program provided that each pharmacy complies with all rules and regulations for a pharmacy-based service program, including maintenance of all required records specific to each pharmacy's drugs.

11.4(2) *Medical director-based service programs.* An Iowa-licensed physician may enter into an agreement with a service program located in the state. The agreement shall be signed by the medical director and the service director and be maintained at the primary program site while the agreement is in effect. The agreement shall include an attestation that the medical director agrees to abide by these rules.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.5(124,147A,155A) Termination of agreement. A written agreement may be terminated at the discretion of either the service program or the party or parties responsible for providing drugs to the service program. Written notification of such termination shall be provided to the other party at least 30 days prior to termination of the agreement.

11.5(1) *Pharmacy-based service programs.* Immediately upon discontinuation of a written agreement, all controlled substances shall be jointly inventoried by the pharmacist in charge of the pharmacy that owns the drugs and the service director or their respective designees. A record of this inventory shall be maintained at the pharmacy for two years from the date of the inventory and shall be available for inspection and copying by the board, its representative, or any other authorized individual. All drugs and devices that are the property of the pharmacy shall be immediately returned to the pharmacy.

11.5(2) *Medical director-based service programs.* Immediately upon discontinuation of a written agreement, all controlled substances shall be jointly inventoried by the medical director and the service director or their respective designees. A record of this inventory shall be maintained by the medical director for two years from the date of the inventory and shall be available for inspection and copying by the board, its representative, or any other authorized individual. All drugs and devices that are the property of the medical director shall be immediately returned to the medical director.

11.5(3) *Transfer of ownership.* If drugs in a service program are to be maintained under the ownership of a new pharmacy or medical director, such transfer of ownership shall be in compliance with 657—Chapter 10, 657—Chapter 17, and federal laws and regulations. Pursuant to rule 657—10.34(124,155A), the transfer of Schedule II controlled substances shall require an executed DEA Form 222.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 0342C**, IAB 10/3/12, effective 11/7/12; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.6(124,147A,155A) Registration required. Rescinded **ARC 3101C**, IAB 6/7/17, effective 7/12/17.
[**ARC 9786B**, IAB 10/5/11, effective 11/9/11]

657—11.7 Reserved.

657—11.8(124,147A,155A) Identification. A log of employees who have access to prescription drugs and to records regarding procurement, storage, and administration of prescription drugs at the service program shall be maintained for two years and be available for inspection and copying by the board, its representative, or any other authorized individual. This log shall include each employee's printed name and signature, printed and signed initials or other unique identification used in service program records, and the employee's level of certification. A service program may maintain an electronic record of employee identification, including the employee's name, signature, unique identification used in the service program records, and level of certification. Such log shall be maintained at the primary program site for at least two years from the date of the employee's last date of employment with the service program and shall be available for inspection and copying by the board, its representative, or any other authorized individual.
[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.9 Reserved.

657—11.10(124,147A,155A) Ownership of prescription drugs. All prescription drugs obtained for use in a service program shall be owned either by a pharmacy or by the medical director of the service program.

11.10(1) *Pharmacy-based service programs.* If the drugs are owned by a pharmacy or more than one pharmacy pursuant to these rules, the service program shall be considered a pharmacy-based service program and shall comply with these rules as they pertain to a pharmacy-based service program.

11.10(2) *Medical director-based service programs.* If the drugs are owned by the medical director, the service program shall be considered a medical director-based service program and shall comply with these rules as they pertain to a medical director-based service program.

11.10(3) *Combination pharmacy-based and medical director-based service programs.* If the service program has entered into both pharmacy-based and medical director-based service program agreements, both the pharmacy and the medical director shall retain separate ownership of the prescription drugs supplied and shall comply with these rules as applicable. The primary program site shall maintain a list that identifies which prescription drugs are owned and supplied by each responsible individual.

11.10(4) *Transfer of ownership.* Any transfer of ownership of prescription drugs and devices in a service program shall be in compliance with 657—Chapter 10, 657—Chapter 17, and federal laws and regulations.
[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.11(124,147A,155A) Policies and procedures.

11.11(1) The service director, the medical director, and the responsible individual shall develop, implement, and adhere to written policies and procedures for the operation and management of the service program with respect to prescription drugs and devices in accordance with these rules. These policies and procedures shall be available for inspection and copying by the board, its representative, or any other authorized individual. The policies and procedures shall be periodically reviewed by the responsible individual, the medical director, and the service director and shall identify the frequency of the review. Documentation of the review shall be maintained.

11.11(2) The policies and procedures shall address, at a minimum, the following:

a. Storage of drugs at the primary program site and any program substations, including appropriate temperature controls , temperature monitoring and response when drugs are exposed to extreme temperatures pursuant to rule 657—11.13(124,147A,155A).

b. Storage of drugs at the primary program site and any program substations, including adequate security to prevent diversion and unauthorized access to drugs and records pursuant to rule 657—11.13(124,147A,155A).

c. Protocols for administration of drugs pursuant to rule 657—11.14(124,147A,155A).

d. Administration of drugs outside the parameters of written protocols pursuant to rule 657—11.15(124,147A,155A).

e. Service program personnel matters including, but not limited to:

(1) Access to prescription drugs and records, identifying level of access based upon employee certification level and scope of practice.

(2) Authority to administer drugs based upon employee certification level and scope of practice.

(3) Authority to order, receive, and distribute prescription drugs and devices.

(4) Initial training and periodic review of the medication policies and procedures.

(5) Identification of registered nurses not employed by the service program who are authorized by the medical director pursuant to Iowa Code section 147A.12 and pursuant to rules of the board of nursing to provide emergency care under the service program's protocol.

f. Process for the return of drugs pursuant to rule 657—11.22(124,147A,155A).

g. Out-of-date and adulterated drugs pursuant to rule 657—11.23(124,147A,155A).

h. Drug and device recalls pursuant to rule 657—11.24(124,147A,155A).

i. Monthly inspections pursuant to rule 657—11.20(124,147A,155A).

j. Record retention as described in rule 657—11.34(124,147A,155A) and other applicable rules of the board.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 0342C**, IAB 10/3/12, effective 11/7/12; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.12 Reserved.

657—11.13(124,147A,155A) Storage. Prescription drugs at primary program sites and program substations shall be stored in designated secure areas that are clean and free of debris, where temperature is appropriately controlled, and in a manner to protect identity and integrity.

11.13(1) *Temperature.* Each drug shall be stored within the temperature range required in the manufacturer labeling. The service program shall utilize a method to provide continuous temperature control or monitoring, such as a temperature indicator, which at a minimum identifies when the drugs have been exposed to extreme temperatures. The service program shall regularly, but at least weekly, verify and document verification that the drugs have not been exposed to extreme temperatures. Drugs that are subjected to extreme temperatures shall not be administered to patients and shall be quarantined and returned to the responsible individual for disposition. Extreme temperatures shall be defined as excessive heat greater than 40 degrees Celsius (104 degrees Fahrenheit) and, if the product requires protection from freezing temperatures, excessive cold less than -10 degrees Celsius (13 degrees Fahrenheit). Disposition of unusable drugs shall be in compliance with rule 657—11.32(124,147A,155A).

11.13(2) *Security.* The security of prescription drugs, records for such drugs, and patient records is the responsibility of the responsible individual and shall provide for the effective control against theft of, diversion of, or unauthorized access to drugs and records. Policies shall identify procedures that will utilize or require the signature of two service employees for each disbursement to ensure accountability for controlled substances.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.14(124,147A,155A) Protocols. Every service program shall utilize department protocols as the standard of care. The service program medical director may authorize an alternative protocol provided the directives are within the EMS provider's scope of practice , are within acceptable medical practice, and have been filed with the department. Prescription drugs shall be administered pursuant only to a written protocol or oral order by an authorized prescriber. A copy of the current protocol shall be provided to and maintained by the responsible individual, the service director, the primary program site and each

program substation and shall be available for inspection and copying by the board, its representative, or any other authorized individual.
[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.15(124,147A,155A) Administration of drugs beyond the limits of a written protocol. Drugs may be administered beyond the limits of a written protocol provided that medical direction from an authorized prescriber has been obtained prior to administration. The authorization shall be recorded in the patient care report documenting the identity of the authorizing prescriber. If an agent of the authorized prescriber relayed the order, the identity of the prescriber's agent, including the agent's first and last names and title, shall also be recorded. The administration of a Schedule II controlled substance in a pharmacy-based service program shall be documented pursuant to rule 657—11.16(124,147A,155A).
[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.16(124,147A,155A) Administration of Schedule II controlled substances—pharmacy-based service program. In a pharmacy-based service program, Schedule II controlled substances may be administered to patients under the care of a service program, including administration beyond the limits of a protocol when authorized pursuant to rule 657—11.15(124,147A,155A), provided that a signed order is delivered by the authorized prescriber to the pharmacy within seven days of the date administration was authorized. The signed order shall contain all of the prescription information required pursuant to Iowa Code section 155A.27. The patient care report may be accepted as the required signed order if the patient care report includes the required prescription information, including an original signature of the authorizing prescriber.
[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.17 and **11.18** Reserved.

657—11.19(124,147A,155A) Patient care reports. Patient care reports shall be maintained at the primary program site or the program substation as required by the bureau and rule 657—11.34(124,147A,155A).
[**ARC 9786B**, IAB 10/5/11, effective 11/9/11]

657—11.20(124,147A,155A) Prescription drugs in service programs. Prescription drugs maintained by a service program shall be owned by an Iowa-licensed pharmacy or the service program's medical director.

11.20(1) *Pharmacy-based service programs.* The pharmacist in charge, the medical director, and the service director shall jointly develop, consistent with the service program's protocol, a list of drugs to be maintained for administration by the service program. The pharmacy shall maintain a current list of all prescription drugs including controlled substances that the pharmacy maintains at the primary program site and at any program substation.

a. Replenishment. The responsible individual, the service director, or designee may request that replenishment supplies of drugs be maintained at the primary program site provided that the pharmacy has been supplied with administration records justifying the order. Records of the administration of Schedule III, IV, and V controlled substances and noncontrolled prescription drugs provided to and maintained at the pharmacy shall include, at a minimum: the patient's name; the name, strength, dosage form, and quantity of the drug administered; and the date of administration. Records of the administration of Schedule II controlled substances provided to and maintained at the pharmacy shall consist of a written prescription including all of the prescription information required pursuant to Iowa Code section 155A.27 or the patient care report if the patient care report includes the required prescription information, including an original signature of the authorizing prescriber. A pharmacist shall verify the accuracy of every drug to be disbursed to the primary program site. Documentation of this verification shall be maintained within the pharmacy records.

b. Replenishment using automated medication distribution system (AMDS). A pharmacy utilizing an automated medication distribution system (AMDS) may authorize replenishment of the service program's drug supplies from the AMDS provided that a pharmacist verifies the drugs stocked in

the AMDS component before the drugs are removed from the pharmacy. Service program personnel authorized to remove drugs from the AMDS for restocking the service program's supplies shall be assigned a unique identification and access code for the purpose of accessing the AMDS. Access by authorized service program personnel shall be restricted to specific drug products authorized for use by the service program. A pharmacist shall, within 72 hours, review the access of and removal of drugs from the AMDS by service program personnel and shall maintain documentation of that review within the pharmacy records.

c. Inspections. The pharmacist in charge shall ensure the completion of a monthly inspection of all prescription drugs maintained by the pharmacy at the primary program site and any program substation. Inspection shall include the removal of outdated or adulterated drugs. All drugs removed from service program stock shall be returned to the pharmacy. Records of inspection shall be maintained for two years from the date of the inspection at the pharmacy. The pharmacist in charge may delegate the completion of the monthly inspection to another pharmacist, a pharmacist-intern, a certified pharmacy technician, or another designee of the pharmacist in charge.

11.20(2) *Medical director-based service programs.* The medical director and the service director shall jointly develop, consistent with the service program's protocol, a list of drugs to be maintained for administration by the service program. The medical director shall maintain a current list of all prescription drugs including controlled substances that the medical director maintains at the primary program site and at any program substation.

a. Replenishment. All drugs procured for administration in a medical director-based service program shall be obtained from an Iowa-licensed wholesaler, pharmacy, or authorized prescriber.

b. Inspections. The medical director shall ensure the completion of a monthly inspection of all prescription drugs maintained by the medical director at the primary program site and any program substation. Inspection shall include the removal of outdated or adulterated drugs. Records of inspection shall be maintained for two years from the date of the inspection at the primary program site or the program substation. The medical director may delegate the completion of the required inspections to the service director or other designee.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 0342C**, IAB 10/3/12, effective 11/7/12; **ARC 1307C**, IAB 2/5/14, effective 3/12/14; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.21 Reserved.

657—11.22(124,147A,155A) Return of drugs. Drugs that have been removed from service program stock shall be returned to the responsible individual. In a pharmacy-based service program, drugs returned from the service program to the pharmacy may be used by the pharmacy for subsequent dispensing or administration provided the drugs are not outdated or adulterated. Records of the return of prescription drugs shall be maintained by the responsible individual for two years from the date of the return.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.23(124,147A,155A) Out-of-date drugs or devices. Any drug or device bearing an expiration date shall not be administered beyond the expiration date of the drug or device. Outdated drugs or devices shall be removed from service program stock and quarantined until such drugs or devices are returned to the responsible individual for disposition.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.24(124,147A,155A) Product recall. Each service program shall have a procedure for removal from service program stock all drugs or devices subject to a product recall. The procedure shall include action appropriate to the direction or requirements of the recall.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.25 Reserved.

657—11.26(124,147A,155A) Controlled substances records.

11.26(1) *Records maintained.* Every inventory or other record required to be maintained under this chapter, 657—Chapter 10, or Iowa Code chapter 124 shall be maintained at the primary program site or the program substation and by the pharmacy if the service program is pharmacy-based. All required records shall be available for inspection and copying by the board, its representative, or any other authorized individual for at least two years from the date of such record. Controlled substances records shall be maintained in a readily retrievable manner. Schedule II controlled substances records shall be maintained separately from all other records of the registrant.

11.26(2) *Receipt and disbursement records in medical director-based service programs.* Any pharmacy or other authorized registrant that provides controlled substances for a medical director-based service program shall provide to the service program a record of the disbursement and maintain a record of the disbursement pursuant to rule 657—10.16(124). The service program shall retain the record on which an authorized individual shall sign and record the actual date of receipt. The record shall include the following:

a. The name of the substance;

b. The strength and dosage form of the substance;

c. The number of units or commercial containers acquired from other registrants, including the date of receipt and the name, address, and DEA registration number of the registrant from whom the substances were acquired;

d. The number of units or commercial containers distributed to other registrants, including the date of distribution and the name, address, and DEA registration number of the registrant to whom the substances were distributed; and

e. The number of units or commercial containers disposed of in any other manner, including the date and manner of disposal and the name, address, and DEA registration number of the registrant to whom the substances were distributed for disposal, if appropriate.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17; **ARC 3637C**, IAB 2/14/18, effective 3/21/18]

657—11.27(124,147A,155A) Ordering Schedule II controlled substances—medical director-based service programs. Except as otherwise provided by 657—subrule 10.17(2) and under federal law, a DEA Form 222, preprinted with the address of the primary program site, is required to be maintained at the primary program site for the acquisition of each supply of a Schedule II controlled substance. The order form shall be executed only by the medical director named on the order form or by an authorized signer designated pursuant to a properly executed power of attorney. A DEA Form 222 shall be dated and signed as of the date the order is submitted for filling. A medical director or authorized signer shall not pre-sign a DEA Form 222 for subsequent completion. All Schedule II order forms shall be maintained at the primary program site and shall be available for inspection and copying by the board, its representative, or any other authorized individual for a period of two years from the date of the record.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17; **ARC 3637C**, IAB 2/14/18, effective 3/21/18]

657—11.28 Reserved.

657—11.29(124,147A,155A) Schedule II controlled substances perpetual inventory. Each service program located in Iowa that administers Schedule II controlled substances shall maintain a perpetual inventory for all Schedule II controlled substances pursuant to the requirements of this rule. All records relating to the perpetual inventory shall be maintained at the primary program site and shall be available for inspection and copying by the board, its representative, or any other authorized individual for a period of two years from the date of the record.

11.29(1) *Record.* The perpetual inventory record may be maintained in a hard-copy or electronic record format. Any electronic record shall provide for hard-copy printout of all transactions recorded in the perpetual inventory record for any specified period of time and shall state the current inventory quantities of each drug at the time the record is printed. A record entry, once recorded, shall not be

changed; any adjustments or corrections shall require entry of a separate record as provided in subrule 11.29(3).

11.29(2) *Information included.* The perpetual inventory record shall identify all receipts and disbursements of Schedule II controlled substances by drug name or by National Drug Code (NDC), including each patient administration, wastage, and return of a drug to the responsible individual. The record of receipt shall also identify the source of the drug, the strength and dosage form, the quantity, the date of receipt, and the name or unique identification of the individual verifying receipt of the drug. The disbursement record shall identify where or to whom the drug is disbursed or administered, the strength and dosage form, the quantity, the date of disbursement or administration, and the name or unique identification of the individual responsible for the disbursement. Receipts and disbursements shall be recorded in the perpetual inventory as soon as practicable but no later than 24 hours after the receipt, disbursement, or administration.

11.29(3) *Adjustments or corrections to the record.* Any adjustments or corrections made to the perpetual inventory shall include the identity of the person making the adjustment or correction and the reason for the adjustment or correction.

11.29(4) *Reconciliation.* The pharmacist in charge or designee in a pharmacy-based service program, or the medical director or designee in a medical director-based service program, shall be responsible for reconciling the perpetual inventory record of all Schedule II controlled substances with the physical inventory at least monthly. Any discrepancy shall be reported within 24 hours of the discovery to the responsible individual for investigation.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.30(124,147A,155A) Controlled substances annual inventory. An accurate inventory shall be taken annually of all controlled substances maintained at the primary program site and program substations. Controlled substances in a pharmacy-based service program shall be included in the pharmacy's annual controlled substances inventory. The inventory record shall identify the drug name or National Drug Code (NDC) and the exact quantity under the control of the service program including drugs in replenishment stock and quarantined stock. The inventory record shall contain the date and time the inventory was taken and the printed name and signature of the individual or individuals responsible for the inventory record. Records of the inventory shall be maintained pursuant to rule 657—11.34(124,147A,155A).

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.31 Reserved.

657—11.32(124,147A,155A) Disposition of controlled substances. Disposition of controlled substances shall be pursuant to the requirements of this rule, rule 657—11.29(124,147A,155A), 657—Chapter 10, and federal regulations. Records shall be maintained at the primary program site and, if the service program is pharmacy-based, records shall be maintained at the pharmacy.

11.32(1) *Outdated, adulterated, or unwanted supply.* Controlled substances shall not be destroyed except as provided in subrule 11.32(2). Any drug that requires disposition shall be quarantined until the drug can be returned to the responsible individual. The responsible individual shall ensure the proper disposition of controlled substances according to the following procedures:

a. The responsible individual shall utilize the services of a DEA-registered and Iowa-licensed disposal firm (reverse distributor), or

b. The responsible individual shall utilize such other means determined and approved by the board.

11.32(2) *Administration wastage.* Except as otherwise specifically provided by federal or state law or rules of the board, the unused portion of a controlled substance resulting from administration to a patient may be destroyed or otherwise disposed of by the administering service program personnel, the medical director, or a pharmacist. Any wastage of a controlled substance shall be conducted in the presence of a responsible adult witness who is an authorized service program employee, a member of the professional or technician pharmacy staff, or a licensed health care professional. A written or electronic record of controlled substance wastage shall be created and maintained at the primary program site and,

if the service program is pharmacy-based, at the pharmacy, for a minimum of two years following the disposition. The record shall include the signatures or other unique identification of the witness and of the individual destroying or otherwise disposing of the wastage of the controlled substance and shall identify the following:

a. The controlled substance wasted;

b. The date of destruction or other disposition;

c. The quantity or estimated quantity of the wasted controlled substance;

d. The source of the controlled substance, including identification of the patient to whom the substance was administered; and

e. If either individual involved in the wastage is not identified in the service program identification log, the legibly printed first and last names and title of the individual.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.33(124,147A,155A) Report of loss or theft of controlled substance. Upon suspicion of any loss or theft of a controlled substance, the service director shall immediately notify the responsible individual. The responsible individual shall provide notice and reporting as required in rule 657—10.21(124).

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17; **ARC 3637C**, IAB 2/14/18, effective 3/21/18]

657—11.34(124,147A,155A) Records. If a service program includes a primary program site and one or more program substations, each record shall identify the specific location to which it applies. Records regarding service program substation activities, including drug supply and administration records, may be maintained at the primary program site but shall clearly identify the program substation to which the records apply. All records regarding prescription drugs and devices in a service program shall be maintained for two years from the date of the activity or record and be available for inspection and copying by the board, its representative, or any other authorized individual.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

These rules are intended to implement Iowa Code chapter 147A and Iowa Code sections 124.301 and 155A.13.

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CHAPTER 13
TELEPHARMACY PRACTICE

657—13.1(155A) Purpose and scope. The purpose of this chapter is to provide standards for the provision of telepharmacy services to patients. These rules provide for pharmaceutical care services at a telepharmacy site utilizing audiovisual technologies that link the telepharmacy site with a managing pharmacy and one or more verifying pharmacists. The telepharmacy site and the managing pharmacy shall be located within Iowa and shall maintain appropriate licensure by the board.
[**ARC 3236C**, IAB 8/2/17, effective 9/6/17]

657—13.2(155A) Definitions. For purposes of this chapter, the following definitions shall apply:

"Board" means the board of pharmacy.

"CSA" or *"CSA registration"* means a registration issued pursuant to Iowa Code section 124.303 and 657—Chapter 10.

"DEA" means the Drug Enforcement Administration of the U.S. Department of Justice.

"Managing pharmacy" means a licensed pharmacy located in Iowa that oversees the activities of one or more telepharmacy sites.

"Telepharmacy" means the practice of pharmacy where pharmaceutical care services are provided using audiovisual technologies linking a telepharmacy site with the managing pharmacy.

"Telepharmacy site" means a licensed pharmacy that is operated by a managing pharmacy and staffed by one or more telepharmacy technicians where pharmaceutical care services, including the storage and dispensing of prescription drugs, drug utilization review, and patient counseling, are provided by a licensed pharmacist through the use of technology.

"Verifying pharmacist" means a remote Iowa-licensed pharmacist or pharmacists who perform any step in the prescription verification and dispensing process including but not limited to: verification of data entry; product selection, packaging, and labeling; drug utilization review; and patient counseling.
[**ARC 3236C**, IAB 8/2/17, effective 9/6/17]

657—13.3(124,155A) Written agreement. The managing pharmacy and the telepharmacy site shall execute and maintain a current written agreement between the pharmacies. If there is no current written agreement between the pharmacies, the telepharmacy site shall immediately notify the board and shall discontinue operations as a telepharmacy site until a current written agreement between the managing pharmacy and the telepharmacy site is executed.

13.3(1) *Contents of agreement.* The written agreement between the managing pharmacy and a telepharmacy site shall include, but may not be limited to, the following:

a. Staffing, to include telepharmacy technician staffing, verifying pharmacist staffing and availability, and on-site pharmacist staffing as needed.

b. Hours of operation of the telepharmacy site and hours of availability of pharmacists at the managing pharmacy.

c. Emergency contact information for the managing pharmacy and the telepharmacy site.

d. A complete description of the audiovisual technology to be utilized to link the managing pharmacy and the telepharmacy site.

e. A provision that, in the event that the telepharmacy technician is not available at the telepharmacy site, that a verifying pharmacist is not available, or that the audiovisual communication connection between the telepharmacy site and the managing pharmacy is not available, the telepharmacy site shall close pending the availability of the technician, the verifying pharmacist, and the communication link or pending the arrival at the telepharmacy site of a pharmacist to provide on-site pharmacy services.

f. Activities and services to be provided by the managing pharmacy at the telepharmacy site.

g. Identification of contact persons to receive, on behalf of the managing pharmacy and the telepharmacy site, notifications and official communications regarding the written agreement. Identification of contact persons shall include delivery addresses and preferred methods of delivery of

the written communications required by this rule and any other communications affecting the written agreement between the managing pharmacy and the telepharmacy.

h. Pharmacy locations, other than the managing pharmacy, where verifying pharmacists may be based or located.

13.3(2) *Termination of agreement.* A managing pharmacy shall provide written notice to the board and to the telepharmacy site 90 days in advance of the managing pharmacy's intent to terminate the agreement between the telepharmacy site and the managing pharmacy. A telepharmacy site shall provide written notice to the board and to the managing pharmacy 90 days in advance of the telepharmacy site's intent to terminate the agreement between the managing pharmacy and the telepharmacy site.

a. New agreement. A new written agreement between a managing pharmacy and the telepharmacy site, including the filing of a new pharmacy license application identifying the new pharmacist in charge, shall be executed within the 90-day advance notification period.

b. No new agreement. If the telepharmacy site is unable to contract with a new managing pharmacy, the telepharmacy site shall, 30 days prior to the expiration of the 90-day advance notification period, implement the prior notification requirements for closing a telepharmacy site as provided in subrule 13.3(3). The telepharmacy site shall cease operations and close at the end of that 30-day closing notification period unless a new written agreement is executed.

13.3(3) *Closing of telepharmacy site.* A telepharmacy site that intends to close the telepharmacy site shall provide written notification to the managing pharmacy and the board as provided in subrule 13.3(2). In addition, the telepharmacy site shall provide written notification to the DEA and to patients and shall comply with all requirements for closing a pharmacy as provided in 657—subrule 8.35(7).

13.3(4) *Closing of managing pharmacy.* A managing pharmacy that intends to close the managing pharmacy shall provide written notification to the telepharmacy site and the board as provided in subrule 13.3(2). In addition, the managing pharmacy shall provide written notification to the DEA and to patients and shall comply with all requirements for closing a pharmacy as provided in 657—subrule 8.35(7). A telepharmacy site that has been managed by the closing pharmacy shall comply with the provisions of subrules 13.3(2) and 13.3(3), as applicable.

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17]

657—13.4(155A) Responsible parties. The responsibilities identified and assigned pursuant to rule 657—8.3(155A) shall be assigned, as appropriate, to the managing pharmacy and the telepharmacy site, by and through their respective owners or license holders, to the pharmacist in charge and to staff pharmacists, including verifying pharmacists. A telepharmacy technician shall share responsibility with the pharmacist in charge, the telepharmacy site, and the verifying pharmacist, as assigned in rule 657—8.3(155A), for all functions assigned to and performed by the telepharmacy technician.

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17]

657—13.5 to **13.7** Reserved.

657—13.8(124,155A) General requirements for telepharmacy site. The telepharmacy site shall maintain a pharmacy license issued by the board. If the telepharmacy site plans to dispense controlled substances, the telepharmacy site shall also maintain a CSA registration and a DEA registration.

13.8(1) *Located in Iowa.* A telepharmacy site shall be located within the state of Iowa.

13.8(2) *Pharmacist in charge.* The pharmacist in charge of the telepharmacy site shall be the pharmacist in charge of the managing pharmacy.

13.8(3) *Security.* A telepharmacy site shall employ methods to prevent unauthorized access to prescription drugs, devices, and pharmacy and patient records. Such methods may include an alarm system and shall include other security systems and methods as provided by these rules. Alarm systems and entry system locks should be disarmed when the telepharmacy site is staffed and open for business. Minimum security methods shall include:

a. Electronic keypad or other electronic entry system into the telepharmacy site or the pharmacy department that requires and records the unique identification of the individual accessing the pharmacy,

including the date and time of access. Complete access records shall be maintained for a minimum of two years beyond the date of access.

b. Secure storage such as a safe.

c. Controlled access to computer records.

d. A continuous system of video surveillance and recording of the pharmacy department that includes maintenance of recordings for a minimum of 60 days following the date of the recording.

13.8(4) *Telepharmacy site signage.* In addition to the patient counseling sign required pursuant to subrule 13.8(5), one or more signs, prominently posted in every prescription pick-up area and clearly visible to the public, shall inform the public that the location is a telepharmacy site supervised by a pharmacist at a remote location. Signage shall include the name, location, and telephone number of the managing pharmacy. The telepharmacy site shall also prominently post the days and times that the telepharmacy is open for business.

13.8(5) *Patient counseling.* Patient counseling as required by rule 657—6.14(155A) shall be provided utilizing the audiovisual technology employed between the telepharmacy site and the managing pharmacy. Every telepharmacy site shall post in every prescription pickup area, in a manner clearly visible to patients, a notice that Iowa law requires the pharmacist to discuss with the patient any new prescriptions dispensed to the patient. The board shall provide a telepharmacy site with the required signage.

13.8(6) *Label requirements.* In addition to the label requirements identified in 657—subrule 6.10(1), the label affixed to or on the dispensing container of any prescription drug or device dispensed by a telepharmacy site pursuant to a prescription drug order shall include, on the primary label or affixed by use of an auxiliary label, the following:

a. The name, telephone number, and address of the telepharmacy site;

b. The name and telephone number of the managing pharmacy.

13.8(7) *Prohibited activities.* In the physical absence of a pharmacist, the following activities are prohibited:

a. Practice of pharmacist-interns or pharmacy support persons at the telepharmacy site, except that a pharmacy support person may deliver prescriptions to patients outside the telepharmacy site but may not engage in prescription delivery or any other activities at the telepharmacy site.

b. Advising patients regarding over-the-counter products unless that advice is communicated directly by a pharmacist to the patient.

c. Dispensing or delivering prescription medications packaged by a technician into patient med paks unless an on-site pharmacist has verified the drugs in the patient med paks.

d. Tech-check-tech practice.

e. Compounding, unless an on-site pharmacist has verified the accuracy and completeness of the compounded drug product.

f. All judgmental activities identified in rule 657—3.23(155A) that a pharmacy technician is prohibited from performing in the practice of pharmacy.

13.8(8) *Continuous quality improvement.* A telepharmacy site shall implement and participate in a continuous quality improvement program pursuant to rule 657—8.26(155A).

13.8(9) *Technology failure.* If the audiovisual technology between the telepharmacy site and the managing pharmacy or the verifying pharmacist is not operational, no prescriptions shall be dispensed from the telepharmacy site to a patient unless a pharmacist is physically present at the telepharmacy site.

13.8(10) *Perpetual controlled substances inventory.* A telepharmacy site that dispenses controlled substances shall maintain a perpetual inventory record of those controlled substances.

a. The perpetual inventory record requirement shall apply to all controlled substances maintained and dispensed by the telepharmacy site and shall not be limited only to Schedule II controlled substances.

b. The perpetual inventory record format and other requirements provided in rule 657—10.33(124,155A) shall apply to the telepharmacy site's perpetual inventory record of controlled substances, with the following exceptions:

(1) The perpetual inventory record shall contain records for all controlled substances, not just Schedule II controlled substances, and

(2) Audit of the perpetual inventory record shall be completed and the physical and perpetual inventories shall be reconciled pursuant to the requirements of 657—subrule 10.33(4) each month as part of the inspection of the telepharmacy site.

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17; **ARC 3862C**, IAB 6/20/18, effective 7/25/18]

657—13.9(155A) General requirements for managing pharmacy.

13.9(1) *Distance to telepharmacy site.* The managing pharmacy shall be located in Iowa and within a 200-mile radius of a telepharmacy site to ensure that the telepharmacy site is sufficiently supported by the managing pharmacy and that necessary personnel or supplies may be delivered to the telepharmacy site within a reasonable period of time of an identified need.

13.9(2) *Emergency preparedness plan.* A managing pharmacy shall develop and include in both the managing pharmacy's and the telepharmacy site's policies and procedures a plan for continuation of pharmaceutical services provided by the telepharmacy site in case of an emergency interruption of the telepharmacy site's services. The plan shall address the timely arrival at the telepharmacy site of necessary personnel or the delivery to the telepharmacy site of necessary supplies within a reasonable period of time following the identification of an emergency need. The plan may provide for alternate methods of continuation of the services of the telepharmacy site including, but not limited to, personal delivery of patient prescription medications from an alternate pharmacy location or on-site pharmacist staffing at the telepharmacy site.

13.9(3) *Pharmacist in charge.* The pharmacist in charge of the managing pharmacy shall be the pharmacist in charge of the telepharmacy site.

13.9(4) *Adequate audiovisual connection.* The pharmacist in charge shall ensure adequate audiovisual connection with the telepharmacy site during all periods when the telepharmacy site is open for business including ensuring confidentiality of communications in compliance with state and federal confidentiality laws.

13.9(5) *Monthly inspection.* The pharmacist in charge or delegate pharmacist shall be responsible for performing a monthly inspection of the telepharmacy site. Inspection reports shall be signed by the individual pharmacist who performed the inspection. Inspection records and reports shall be maintained at the telepharmacy site for two years following the date of the inspection. A copy of the inspection report shall be provided to and maintained at the managing pharmacy. The monthly inspection shall include, but may not be limited to, the following:

a. Audit and reconciliation of controlled substances perpetual and physical inventories.

b. Audit of electronic entry system and records.

c. Verification that the video recording system is functioning properly and that the recordings are maintained and available for at least 60 days past the date of the recording.

d. Compilation of a record of the number of prescriptions filled, the number of on-site pharmacist hours, and the number of hours the pharmacy site was open for business during the preceding month.

e. Review of written policies and procedures and verification of compliance with those policies and procedures.

f. Ensuring compliance with and review of records in the continuous quality improvement program, following up with responsible personnel to address issues identified by incident reports to prevent future incidents.

g. Review of records of the receipt and disbursement of prescription drugs, including controlled substances, to ensure compliance with record-keeping requirements.

h. Inspection of drug supplies and storage areas to ensure removal and quarantine of outdated drugs.

i. Inspection of stock drug supplies and storage areas to ensure drugs are maintained in a manner to prevent diversion and maintain the integrity of the drugs, verifying that the temperatures of storage areas are appropriate for the stored drugs and equipment.

j. Inspection of pharmacy and storage areas and shelves to ensure areas and shelves are clean and free of pests and other contaminants.

13.9(6) *On-site pharmacist staffing.* In an effort to promote public health, the telepharmacy site shall be staffed by a pharmacist for at least 16 hours per month. While on site, the pharmacist shall make available to the community general health care services, which may include, but not necessarily be limited to, immunizations, medication therapy management, or health screenings, as deemed necessary and appropriate by the pharmacist in charge and as provided by policies and procedures.

a. If a pharmacist will be available at the telepharmacy site to provide in-person patient services, a consistent schedule of the pharmacist's availability shall be established and published.

b. Signage identifying the days and times when a pharmacist is on site and available to patients shall be conspicuously posted at the telepharmacy site and may be published by other means, as deemed appropriate.

c. Notice that the pharmacist will not be present at the telepharmacy site during any routinely scheduled and posted on-site availability shall be provided to the public in advance of the absence except as provided in the emergency preparedness plan.

d. If the average number of prescriptions dispensed per day by the telepharmacy site exceeds 150 prescriptions, the telepharmacy site shall provide on-site pharmacist staffing 100 percent of the time the pharmacy is open for business and shall, within ten business days, apply to the board for licensure as a general pharmacy. The average number of prescriptions dispensed per day shall be determined by averaging the number of prescriptions dispensed per day over the previous 90-day period.

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17]

657—13.10(155A) General requirements for verifying pharmacist. A verifying pharmacist shall maintain a current and active license to practice pharmacy in Iowa.

13.10(1) *Location of verifying pharmacist.* The verifying pharmacist who is performing patient counseling shall be physically located within the managing pharmacy or another pharmacy licensed to operate a pharmacy in Iowa.

13.10(2) *Adequate audiovisual connection.* The verifying pharmacist shall ensure adequate audiovisual connection with the telepharmacy site during all periods when the pharmacist is responsible for verifying telepharmacy site activities and practices, including ensuring confidentiality of communications in compliance with state and federal confidentiality laws.

13.10(3) *Verifying pharmacist training.* A verifying pharmacist shall be adequately trained on the use of the technology to ensure accurate verification and patient counseling and shall review and understand the policies and procedures of the managing pharmacy and the telepharmacy site.

13.10(4) *Patient refusal of counseling.* If a patient or patient's caregiver refuses patient counseling, the refusal shall be directly communicated by the patient or patient's caregiver to the pharmacist through audiovisual communication. A technician may not accept and communicate a refusal of patient counseling from the patient or patient's caregiver to the pharmacist.

13.10(5) *Reference library.* A verifying pharmacist shall have access to all required references applicable to the telepharmacy services provided at the telepharmacy site.

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17]

657—13.11(155A) General requirements for telepharmacy technician. A telepharmacy technician shall maintain current national certification and registration in good standing with the board as a certified pharmacy technician.

13.11(1) *Practice experience.* Before practicing in a telepharmacy site, a telepharmacy technician shall have completed a minimum of 2,000 hours of practice experience as a certified pharmacy technician, at least 1,000 hours of which shall be practicing in an Iowa-licensed pharmacy and 160 hours of which shall be practicing in a managing pharmacy.

13.11(2) *Training.* In addition to training required of all pharmacy technicians, a telepharmacy technician shall complete the following minimum training requirements before practicing in a telepharmacy site. Records of telepharmacy technician training shall be documented and maintained by the telepharmacy site.

a. Review and understanding of the policies and procedures of the managing pharmacy.

b. Review and understanding of the policies and procedures of the telepharmacy site.

c. Review and understanding of these rules for telepharmacy practice.

d. Review and understanding of pharmacy technician rules, 657—Chapter 3.

e. Understanding of the operation of the audiovisual technologies to be utilized at both pharmacies.

f. Training at the telepharmacy site under the direct supervision of an on-site verifying pharmacist. Training shall include operation and use of the audiovisual technology and other means of communication between the telepharmacy site and the managing pharmacy and all daily operations from unlocking and opening the telepharmacy site to closing and locking the telepharmacy site at the end of the business day. If the telepharmacy site is protected by one or more alarm systems, training shall include how to disarm and engage the alarm system or systems.

13.11(3) *Continuing education.* Beginning with the first full two-year continuing education period for renewal of the technician's national pharmacy technician certification after beginning practice as a telepharmacy technician, and for each subsequent renewal of national certification for as long as the technician continues to practice as a telepharmacy technician, the technician shall complete two hours of continuing education in each of the following activities. These continuing education requirements shall not be in addition to the total continuing education credits required to maintain national certification.

a. Patient safety/medication errors.

b. Pharmacy law.

13.11(4) *Identification.* The telepharmacy technician shall, at all times when the technician is practicing at the telepharmacy site and the telepharmacy site is open for business, wear a name badge or tag identifying the technician. The badge or tag shall include, at a minimum, the technician's first name and title. The name badge or tag shall be so designed and worn that the technician's name and title are clearly visible to the public at all times.

13.11(5) *Adequate audiovisual connection.* The telepharmacy technician shall ensure adequate audiovisual connection with the managing pharmacy during all periods when the telepharmacy site is open for business, including ensuring confidentiality of communications in compliance with state and federal confidentiality laws.

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17]

657—13.12 to **13.15** Reserved.

657—13.16(124,155A) Telepharmacy site—initial application.

13.16(1) *License application.* A telepharmacy site shall complete and submit to the board a limited use/telepharmacy license application and fee as provided in rule 657—8.35(155A). In addition to the application and fee, the telepharmacy site shall include the additional information identified in this rule.

13.16(2) *CSA registration application.* If controlled substances will be dispensed from the telepharmacy site, the telepharmacy site shall complete and submit, with the limited use/telepharmacy license application and fee, the CSA registration application and fee as provided in rule 657—10.1(124).

13.16(3) *Identification of managing pharmacy.* The telepharmacy site application shall include identification of the managing pharmacy, including pharmacy name, license number, address, telephone number, pharmacist in charge, and a statement from the managing pharmacy or pharmacist in charge indicating that the managing pharmacy has executed a written agreement to provide the required services and oversight to the telepharmacy site.

13.16(4) *Distance to nearest general pharmacy.* The telepharmacy site application shall identify the nearest licensed pharmacy that dispenses prescription drugs to outpatients and shall provide evidence identifying the total driving distance between the proposed telepharmacy site and the nearest currently licensed general pharmacy.

a. If the distance between the proposed telepharmacy site and the nearest currently licensed general pharmacy is less than ten miles, the telepharmacy site shall submit a request for waiver of the distance requirement. The process and requirements for a request for waiver are identified in subrule 13.16(8).

b. The distance requirement shall not apply under any of the following circumstances:

(1) The telepharmacy site was approved by the board and operating as a telepharmacy site prior to July 1, 2016.

(2) The proposed telepharmacy site is located within a hospital campus, and services will be limited to inpatient dispensing.

(3) The proposed telepharmacy site is located on property owned, operated, or leased by the state.

13.16(5) *Written agreement.* The telepharmacy site application shall include the written agreement between the telepharmacy site and the managing pharmacy as described in subrule 13.3(1).

13.16(6) *Key personnel.* The telepharmacy site application shall identify key personnel including the pharmacist in charge of the managing pharmacy and the telepharmacy site and the telepharmacy technician or technicians at the telepharmacy site. Identification shall include the names, the license or registration numbers, and the titles of the key personnel. Telepharmacy technician identification shall also include a copy of the telepharmacy technician's current national certification or other verification of the telepharmacy technician's current national certification.

13.16(7) *Audiovisual technology.* A description of the audiovisual technology system to be used to link the managing pharmacy and the telepharmacy site, including built-in safeguards relating to verification of the accuracy of the dispensing processes. Safeguards shall include but may not be limited to:

a. Requiring a verifying pharmacist to review and compare the electronic image of any new prescription with the data entry record of the prescription prior to authorizing the telepharmacy site's system to print a prescription label and prior to the telepharmacy technician's filling of the prescription at the telepharmacy site.

b. Requiring the technician to use barcode technology at the telepharmacy site to verify the accuracy of the drug to be dispensed.

c. Requiring remote visual confirmation by a verifying pharmacist of the drug stock bottle and the drug to be dispensed prior to the dispensing of the prescription at the telepharmacy site.

d. Ensuring that the telepharmacy site's system prevents a prescription from being sold and delivered to a patient before the verifying pharmacist has performed a final verification of the accuracy of the prescription and released the prescription for sale and delivery at the telepharmacy site.

13.16(8) *Request for distance waiver.* The board shall consider a request for waiver of the distance requirement between the proposed telepharmacy site and the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients if the petitioner can demonstrate to the board that the proposed telepharmacy site is located in an area where there is limited access to pharmacy services and that there exist compelling circumstances that justify waiving the distance requirement.

a. The request for waiver shall be prepared and shall include the elements of a request for waiver or variance identified in 657—Chapter 34.

b. In addition to the requirements of 657—Chapter 34, the request for waiver shall include evidence and specific information regarding each of the following, if applicable. If an item identified below does not apply to the proposed telepharmacy site, the request for waiver shall specifically state that the item does not apply.

(1) That the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients is open for business for limited hours or fewer hours than the proposed telepharmacy site.

(2) That the proposed telepharmacy site intends to provide services not available from the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients.

(3) That access to the nearest currently licensed general pharmacy that dispenses prescription drugs to outpatients is limited. A description of how the proposed telepharmacy site will improve patient access to pharmacy services shall be included.

(4) That limited access to pharmacy services is affecting patient safety.

(5) That there are transportation barriers to services from the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients.

(6) That the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients is closing.

(7) That the proposed telepharmacy site is located in an area of the state where there is limited access to pharmacy services.

c. The board shall consider a request for waiver of the distance requirement during any open session of a meeting of the board. One or more representatives of the parties to the waiver request, including representatives of the proposed telepharmacy site, the managing pharmacy, and the nearest currently licensed general pharmacy, shall be invited and encouraged to attend the meeting at which the waiver request is scheduled for consideration to be available to respond to any questions.

d. The board's decision to grant or deny the request for waiver of the distance requirement shall be a proposed decision and shall be reviewed by the director of the department of public health.

(1) The director shall have the power to approve, modify, or veto the board's proposed decision regarding the waiver request.

(2) The director's decision on a waiver request shall be considered final agency action.

(3) The director's decision (final agency action) shall be subject to judicial review under Iowa Code chapter 17A.

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17]

657—13.17(124,155A) Changes to telepharmacy site or managing pharmacy. Except as specifically provided by these rules, a change to a telepharmacy site shall require compliance with the licensure and notification requirements of the specific type of change identified in 657—subrules 8.35(6) and 8.35(7). A change affecting the CSA registration shall comply with the appropriate requirements of rule 657—10.11(124).

13.17(1) *Change of pharmacist in charge.* A change of pharmacist in charge shall require submission of a pharmacy license application for the managing pharmacy and the telepharmacy site as provided by 657—subrule 8.35(6).

13.17(2) *Closing or selling of pharmacy.* A telepharmacy site or managing pharmacy that intends to close or sell the pharmacy practice shall comply with all requirements for closing or selling a pharmacy found at 657—subrules 8.35(6) and 8.35(7) regarding ownership change and closing a pharmacy, including all advance notification requirements. A purchaser of a telepharmacy site shall complete and submit applications and supporting information as provided in rule 657—13.16(124,155A). A closing pharmacy shall also comply with the requirements of subrule 13.3(3) or 13.3(4), as appropriate.

13.17(3) *Location change.* A telepharmacy site that intends to move to and to provide telepharmacy services from a new location that is outside the community wherein the telepharmacy site has been located shall comply with the requirements of subrule 13.17(2) for closing a pharmacy and shall submit applications and supporting information as provided in rule 657—13.16(124,155A). A managing pharmacy that intends to move to a new location shall comply with the requirements of 657—subrules 8.35(4), 8.35(6), and 8.35(7), as appropriate.

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—13.18(155A) Opening of traditional pharmacy. If a pharmacy licensed as a general, hospital, or limited use pharmacy opens for business within ten miles of an existing and operating telepharmacy site, the telepharmacy site may continue to operate as a telepharmacy site and shall not be required to close due to the proximity of the new pharmacy.

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17]

657—13.19 and **13.20** Reserved.

657—13.21(124,155A) Policies and procedures. In addition to policies and procedures required for the specific services provided and identified in other chapters of board rules, both the managing pharmacy and the telepharmacy site shall develop, implement, and adhere to written policies and procedures for the operation and management of the specific pharmacy's operations.

13.21(1) *Minimum requirements.* Policies and procedures shall define the frequency of review, and written documentation of review by the pharmacist in charge shall be maintained. Policies and procedures shall address, at a minimum, the following:

a. Procedures ensuring that a record is made and retained identifying the pharmacist who verified the accuracy of the prescription including the accuracy of the data entry, the selection of the correct drug, the accuracy of the label affixed to the prescription container, and the appropriateness of the prescription container.

b. Procedures ensuring that a record is made and retained identifying the pharmacist who performed the drug utilization review as provided by rule 657—8.21(155A).

c. Procedures ensuring that a record is made and retained identifying the pharmacist who provided counseling to the patient or the patient's caregiver pursuant to rule 657—6.14(155A).

d. Procedures ensuring that a record is made and retained identifying the technician who filled the prescription.

e. Procedures ensuring adequate security to prevent unauthorized access to prescription drugs and devices and to confidential records.

f. Procedures regarding procurement of drugs and devices, including who is authorized to order or receive drugs and devices, from whom drugs and devices may be ordered and received, and the required method for documentation of the receipt of drugs and devices.

g. Procedures ensuring appropriate and safe storage of drugs at the telepharmacy site, including appropriate temperature controls.

h. Procedures identifying the elements of a monthly inspection of the telepharmacy site by the pharmacist in charge or designated pharmacist, including requirements for documentation and retention of the results of each inspection.

i. Procedures for the temporary quarantine of out-of-date and adulterated drugs from dispensing stock and the subsequent documented disposal of those drugs.

j. Procedures and documentation required in the case of return to the telepharmacy of a drug or device.

k. Procedures for drug and device recalls.

13.21(2) *Availability.* Policies and procedures shall be available for inspection and copying by the board or the board's representative at the location to which the policies and procedures apply.

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17]

657—13.22(155A) Reports to the board. The board may periodically request information regarding the services provided by a telepharmacy site.

13.22(1) *Timeliness.* A telepharmacy site shall complete and submit the requested information in a timely manner as requested by the board. The board shall allow a reasonable amount of time for a telepharmacy site to complete and submit the requested information.

13.22(2) *Information to include.* Information requested may include, but may not necessarily be limited to, the following:

a. The number of prescriptions dispensed from the telepharmacy site over a specified period of time.

b. The number of hours a pharmacist was physically present at the telepharmacy site over a specified period of time.

c. The number of hours the telepharmacy site was open for business over a specified period of time.

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17]

657—13.23(124,155A) Records. Every inventory or other record required to be kept under Iowa Code chapters 124 and 155A or rules of the board shall be kept by the telepharmacy site and be available for inspection and copying by the board or its representative for at least two years from the date of the inventory or record except as specifically identified by law or rule. Controlled substances records shall be maintained in a readily retrievable manner in accordance with federal requirements and 657—Chapter 10.

13.23(1) *Dispensing record.* As provided in rule 657—13.21(124,155A), a written or electronic record identifying the pharmacist who verified the prescription, the pharmacist who provided counseling

to the patient or the patient's caregiver, and the pharmacy technician who filled the prescription shall be maintained for every prescription fill dispensed by the telepharmacy site.

13.23(2) *On-site pharmacist staffing.* A written or electronic record of the number of prescriptions filled, the number of on-site pharmacist hours, and the number of hours the telepharmacy site was open for business each month shall be maintained by the telepharmacy site.

13.23(3) *Pharmacy access.* Records identifying, by unique identification of the individual accessing the pharmacy department, including the date and time of access, shall be maintained for two years beyond the date of access.

13.23(4) *Monthly inspection.* Reports of the monthly inspection of the telepharmacy site shall be maintained at the telepharmacy site for two years following the date of the inspection. A copy of the inspection report shall be provided to and maintained at the managing pharmacy for two years following the date of the inspection.

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17]

These rules are intended to implement Iowa Code sections 124.301, 147.107, 155A.3, 155A.6A, 155A.13, 155A.14, 155A.19, 155A.28, 155A.31, 155A.33, and 155A.41.

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CHAPTER 17
WHOLESALE DRUG LICENSES

657—17.1(155A) Definitions.

"Authorized collection program" means a program administered by a registrant that has modified its registration with DEA to collect controlled substances for the purpose of disposal. Federal regulations for such programs can be found at www.deadiversion.usdoj.gov/drug_disposal/. Modification to the registrant's Iowa controlled substances Act registration shall not be required.

"Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

"Blood component" means that part of blood separated by physical or mechanical means.

"Board" means the Iowa board of pharmacy.

"DEA" means the United States Department of Justice, Drug Enforcement Administration.

"Distribute" means the delivery of a prescription drug or device.

"Drug sample" means a drug that is distributed without monetary consideration to a pharmacist or practitioner. "Drug sample" does not include drugs intended for patients who would otherwise not receive needed drugs due to their inability to pay.

"Manufacturer" means a person or business engaged in the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes packaging or repackaging of the substances or labeling or relabeling of the substances' containers.

"Prescription drug" means any of the following:

1. A substance for which federal or state law requires a prescription before it may be legally dispensed to the public.
2. A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with one of the following statements:
   - Caution: Federal law prohibits dispensing without a prescription.
   - Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
   - Rx only.
3. A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by a practitioner only.

"Proprietary medicine" or *"over-the-counter (OTC) medicine"* means a nonnarcotic drug or device that may be sold without a prescription and that is labeled and packaged in compliance with applicable state or federal law.

"Reverse distribution" means the receipt of prescription drugs including controlled substances, whether received from Iowa locations or shipped to Iowa locations, for the purposes of destroying the drugs or returning the drugs to their original manufacturers or distributors.

"Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

1. The sale, purchase, or trade of a drug or an offer to sell, purchase or trade a drug for emergency medical reasons. For purposes of this chapter, "emergency medical reasons" includes transfers of prescription drugs by a pharmacy to another pharmacy to alleviate a temporary shortage;
2. The sale, purchase or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription;
3. The lawful distribution of drug samples by manufacturers' representatives or wholesale salespersons;
4. The sale, purchase or trade of blood and blood components intended for transfusion; or
5. Intracompany sales.

"Wholesale distributor" or *"wholesaler"* means a person or business operating or maintaining, either within or outside this state, a manufacturing plant, wholesale distribution center, wholesale business, or any other business in which prescription drugs, medicinal chemicals, medicines, or poisons are sold, manufactured, dispensed, stocked, exposed, or offered for sale at wholesale in this

state. "Wholesaler" includes, but is not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; reverse distributors; and pharmacies that conduct wholesale distributions exceeding 5 percent of gross annual sales of prescription drugs. "Wholesaler" does not include those wholesalers who sell only OTC medicines or manufacturers' representatives lawfully distributing drug samples to authorized practitioners.

"Wholesale salesperson" or *"manufacturer's representative"* means an individual who takes purchase orders on behalf of a wholesaler for prescription drugs, medicinal chemicals, medicines, or poisons. "Manufacturer's representative" also means a person designated by a pharmaceutical manufacturer to lawfully distribute drug samples to authorized practitioners.

[**ARC 2408C**, IAB 2/17/16, effective 3/23/16]

657—17.2 Reserved.

657—17.3(155A) Wholesale drug license. Every wholesaler as defined in rule 657—17.1(155A), wherever located, that engages in wholesale distribution into, out of, or within this state must be licensed by the board in accordance with the laws and rules of Iowa before engaging in wholesale distribution of prescription drugs. Where operations are conducted at more than one location by a single wholesaler, each such location shall be separately licensed in Iowa. A wholesaler located within Iowa that engages in wholesale distribution of or collection via an authorized collection program of controlled substances shall also register pursuant to 657—Chapter 10.

17.3(1) *Application form.* Application for licensure and license renewal shall be on forms provided by the board. Application for wholesale drug licensure shall require an indication of the type of wholesale operation and the wholesaler ownership classification. If the owner is a sole proprietorship (100 percent ownership), the name and address of the owner shall be indicated. If the owner is a partnership or limited partnership, the names and addresses of all partners shall be listed or attached. If the owner is a corporation, the names and addresses of the officers and directors of the corporation shall be listed or attached. Any other wholesaler ownership classification shall be further identified and explained on the application. The name, address, and telephone numbers of at least one contact person for the licensed facility shall be identified. A list of all states in which the wholesaler is licensed and all trade or business names used by the wholesaler shall be included on or with the application. The application shall identify, if the wholesaler is located outside Iowa, applicable home state license information and DEA and FDA license or registration information. The application shall also provide information regarding any past criminal convictions or adverse actions against licenses or registrations held by the licensee or facility managers.

17.3(2) *License expiration and renewal.* A wholesale drug license shall be renewed before January 1 of each year. The fee for a new or renewal license shall be $270.

a. Late payment penalty. Failure to renew the license before January 1 shall require payment of the renewal fee and a penalty fee of $270. Failure to renew the license before February 1 following expiration shall require payment of the renewal fee and a penalty fee of $360. Failure to renew the license before March 1 following expiration shall require payment of the renewal fee and a penalty fee of $450. Failure to renew the license before April 1 following expiration shall require payment of the renewal fee and a penalty fee of $540 and may require an appearance before the board. In no event shall the combined renewal fee and penalty fee for late renewal of a wholesale drug license exceed $810.

b. Delinquent license. If a license is not renewed before its expiration date, the license is delinquent and the licensee may not operate or do business in Iowa until the licensee renews the delinquent license. A drug wholesaler who continues to do business in Iowa without a current license may be subject to disciplinary sanctions pursuant to the provisions of 657—subrule 36.1(4).

17.3(3) *Inspection of new wholesale drug distribution facility.* If a new wholesale drug distribution location within Iowa was not a licensed wholesale drug distribution site immediately prior to the proposed opening of the new wholesale facility, the location shall require an on-site inspection by

a pharmacy board inspector prior to the issuance of the wholesale drug license. The purpose of the inspection is to determine compliance with requirements pertaining to space, equipment, drug storage safeguards, and security. Inspection may be scheduled anytime following submission of necessary license and registration applications and prior to beginning wholesale drug distribution. Prescription drugs, including controlled substances, may not be delivered to a new wholesale drug distribution facility prior to satisfactory completion of the opening inspection.

17.3(4) *Wholesale drug license changes.*

a. Ownership change. When ownership of a licensed drug wholesaler changes, the licensee shall submit to the board written notification including the name, address, and license number of the wholesaler and the effective date of the change. Notification shall also identify the new ownership classification and the owners, partners, or corporate officers as indicated in subrule 17.3(1). In those cases in which the wholesaler is owned by a corporation, the sale or transfer of all stock of the corporation does not constitute a change of ownership provided the corporation that owns the wholesaler continues to exist following the stock sale or transfer. A new license shall not be required for a change of ownership.

b. Name or location change. When a licensed drug wholesaler changes its name or location, a new wholesale drug license application with a license fee as provided in 17.3(2) shall be submitted to the board office. Upon receipt of the fee and properly completed application, the board will issue a new license certificate. The old license certificate shall be returned to the board office within ten days of the change of name or location. A change of wholesaler location within Iowa, if the new location was not a licensed drug wholesaler immediately prior to the relocation, shall require an on-site inspection of the new location as provided in subrule 17.3(3).

17.3(5) *Drug wholesaler closing.* A licensee discontinuing wholesale distribution of prescription drugs in or into Iowa shall submit to the board, with the current wholesale drug license certificate, written notification indicating the effective date of closing or discontinuing business in Iowa. If the drug wholesaler had been engaged in the distribution of controlled substances in Iowa, the written notification shall identify by name, address, and appropriate license numbers the facility or facilities to which controlled substances records and any final inventory of controlled substances have been transferred.

17.3(6) *Failure to complete licensure process.* An application for a wholesale drug license, including an application for registration pursuant to 657—Chapter 10, if applicable, will become null and void if the applicant fails to complete the licensure process within six months of receipt by the board of the required applications. The licensure process shall be complete upon the wholesaler's opening for business at the licensed location following an inspection rated as satisfactory by an agent of the board if such an inspection is required pursuant to this rule. When an applicant fails to timely complete the licensure process, fees submitted with applications will not be transferred or refunded.

[**ARC 0504C**, IAB 12/12/12, effective 1/16/13; **ARC 2408C**, IAB 2/17/16, effective 3/23/16]

657—17.4(155A) Minimum qualifications. The board will consider the following factors in determining eligibility for licensure of persons or businesses that engage in the wholesale distribution of prescription drugs:

1. Any convictions of the applicant under federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
2. Any felony convictions of the applicant under federal, state, or local laws;
3. The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;
4. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;
5. Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;
6. Compliance with licensing requirements under previously granted licenses, if any;

7. Compliance with the requirements to maintain or make available to the board, its agents or authorized personnel, or to federal, state, or local law enforcement officials those records required to be maintained by wholesalers; and

8. Any other factors or qualifications the board considers relevant to and consistent with public health and safety.

657—17.5(155A) Personnel. Licensed wholesalers shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications. The wholesaler shall employ personnel with the education or experience appropriate to the responsibilities of the position held by the individual.

657—17.6(155A) Responsibility for conduct. A licensed drug wholesaler shall be held responsible for actions of the wholesaler's managerial agent when the conduct of the agent may fairly be assumed to represent the policy of the wholesaler. "Managerial agent" includes, but is not necessarily limited to, an officer or director of a corporation or an association or a partner of a partnership, and includes a person having management responsibility for submissions to the FDA regarding the development or approval of any drug product; the production, quality assurance, or quality control of any drug product; or research and development of any drug product.

17.6(1) *Misrepresentative deeds.* A managerial agent shall not make any statement intended to deceive, misrepresent, or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in the manufacture, distribution, or marketing of prescription drugs.

17.6(2) *Unethical conduct or behavior.* A managerial agent shall not exhibit unethical behavior in connection with the manufacture, distribution, or marketing of prescription drugs or refuse to provide reasonable information or answer reasonable questions for the benefit of a health professional or a patient. Unethical behavior shall include, but not be limited to, the following acts: verbal abuse, coercion, intimidation, harassment, sexual advances, threats, degradation of character, indecent or obscene conduct, and theft.

657—17.7(124,155A) Distribution to authorized licensees. A wholesaler shall be responsible for verifying, prior to the distribution of a prescription drug, the authority of the person or business to whom the distribution is intended. Such verification may include, but is not limited to, obtaining a copy of the license under which the person or business claims authority to possess the prescription drug or contacting the appropriate licensing authority for verification of the licensee's authority to possess the prescription drug.

657—17.8(124,155A) Written policies and procedures. Wholesalers shall establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesalers shall also include in their written policies and procedures the following:

17.8(1) *Oldest stock distributed first.* A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.

17.8(2) *Recalls and market withdrawals.* A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

a. Any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement agency or other government agency, including the board;

b. Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

c. Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

17.8(3) *Emergency and disaster plan.* A procedure to ensure that wholesalers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

17.8(4) *Outdated drugs.* A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs.

17.8(5) *Exception.* The procedure required by subrule 17.8(1) does not apply to reverse distribution operations. All other procedures addressed in this rule are required of reverse distribution operations.

17.8(6) *Drugs supplied to salesperson/representative.* If supplying drugs to wholesale salespersons or manufacturers' representatives, a procedure directing that the security, storage, and record-keeping requirements contained in these rules shall be maintained by those wholesale salespersons or manufacturers' representatives.

657—17.9(155A) Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

1. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
2. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
3. Have a quarantine area for storage of outdated, damaged, unsafe, deteriorated, misbranded, or adulterated prescription drugs; for drugs that are in immediate or sealed outer or sealed secondary containers that have been opened; for drugs that have been identified as being defective or are believed to be defective; and for drugs that do not meet the FDA-approved criteria for the product;
4. Be maintained in a clean and orderly condition;
5. Be free from infestation by insects, rodents, birds, or vermin of any kind.

657—17.10(124,155A) Security.

17.10(1) *Secure from unauthorized entry.* All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

a. Access from outside the premises shall be kept to a minimum and be well controlled.

b. The outside perimeter of the premises shall be well lighted.

c. Entry into areas where prescription drugs are held shall be limited to authorized personnel.

17.10(2) *Alarm.* All facilities shall be equipped with an alarm system to deter entry after hours.

17.10(3) *Security system.* All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

17.10(4) *Authorized collection program.* Licensees that are authorized to administer a controlled substances collection program shall provide security pursuant to 657—Chapter 10 and federal regulations.

[**ARC 2408C**, IAB 2/17/16, effective 3/23/16]

657—17.11(155A) Storage. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs or with requirements in the current edition of an official compendium.

17.11(1) *Controlled room temperature.* If no storage requirements are established for a prescription drug, the drug may be held at "controlled room temperature" to help ensure that its identity, strength, quality, and purity are not adversely affected. "Controlled room temperature" means the room temperature is maintained thermostatically between 15 degrees and 30 degrees Celsius (59 degrees and 86 degrees Fahrenheit).

17.11(2) *Documentation.* Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document proper storage of prescription drugs.

17.11(3) *Exception.* The storage requirements of this rule do not apply to reverse distribution operations.

657—17.12 Reserved.

657—17.13(155A) Drugs in possession of representatives. If a wholesaler is supplying samples or other forms of prescription drugs to wholesale salespersons or manufacturers' representatives, the wholesaler shall be responsible for ensuring that those representatives maintain distribution records and maintain the drugs under appropriate security and storage conditions pursuant to the requirements of these rules.

657—17.14(155A) Examination of materials.

17.14(1) *Receipt shipment.* Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

17.14(2) *Outgoing shipment.* Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

17.14(3) *Type of inspection.* Examination or inspection shall be completed in a manner to ensure the stated intent of this rule. Inspection may be completed by use of electronic surveillance or personal examination.

17.14(4) *Authorized collection program.* Substances, including controlled substances, collected through an authorized collection program shall not be examined, inspected, counted, sorted, inventoried, or otherwise handled.

[**ARC 2408C**, IAB 2/17/16, effective 3/23/16]

657—17.15(155A) Returned, damaged, and outdated prescription drugs.

17.15(1) *Quarantine required.* Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to the supplier.

17.15(2) *Seal opened.* Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

17.15(3) *Drug safety, purity uncertain.* Unless examination, testing, or other investigation proves that a drug meets appropriate standards of safety, identity, strength, quality, and purity, a prescription drug that has been returned under conditions that cast doubt on the drug's safety, identity, strength, quality, or purity shall be destroyed or returned to the supplier. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesaler shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the conditions of the drug and its container, carton, or labeling as a result of storage or shipping.

17.15(4) *Exception.* The requirements of this rule do not apply to reverse distribution operations.

657—17.16(124,155A) Record keeping. Wholesalers shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs, including outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

17.16(1) *Transaction records.* Transaction records shall include the following information:

a. The source of the drugs, including the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped;

b. The identity and quantity of the drugs received and distributed or disposed of;

c. The dates of receipt and distribution or other disposition of the drugs; and

d. If a distribution transaction, the recipient of the drugs, including the name and principal address of the purchaser or transferee and the address to which the drugs were shipped.

17.16(2) *Records maintained.* Inventories and records shall be made available for inspection and photocopying by any authorized official of the board or of any governmental agency charged with enforcement of these rules for a period of two years following disposition of the drugs. The annual inventory of controlled substances shall be maintained for a minimum of two years from the date of the inventory.

17.16(3) *Inspection of records.* Records described in this rule that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be available for inspection within two working days of a request by an authorized official of the board or of any governmental agency charged with enforcement of these rules.

17.16(4) *Confidentiality of patient information.* A wholesaler shall obtain and maintain patient-specific data only as necessary for the health and safety of the patient. Any patient-specific information in the possession of a wholesaler shall be maintained in compliance with the patient confidentiality and security requirements of rules 657—8.16(124,155A) and 657—21.2(124,155A).

17.16(5) *Authorized collection program.* A licensee that is authorized to administer a collection program shall maintain all records and inventories as required by 657—Chapter 10, this chapter, and federal regulations.

[**ARC 8669B**, IAB 4/7/10, effective 5/12/10; **ARC 2408C**, IAB 2/17/16, effective 3/23/16]

657—17.17(124,155A) Compliance with federal, state, and local laws. Wholesalers shall operate in compliance with applicable federal, state, and local laws, rules, and regulations.

17.17(1) *Access by authorized officials.* Wholesalers shall permit the board and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials shall be required to show appropriate identification prior to being permitted access to wholesalers' premises and delivery vehicles.

17.17(2) *Controlled substance registrations.* Wholesalers that deal in controlled substances shall register with the appropriate state controlled substance authority and with the Drug Enforcement Administration (DEA) and shall comply with all applicable federal, state, and local laws, rules, and regulations.

657—17.18(155A) Discipline. Pursuant to 657—Chapters 35 and 36, the board may deny, suspend, or revoke a wholesale drug license for any violation of Iowa Code chapter 124, 124B, 126, 155A, or 205 or a rule of the board promulgated thereunder.

[**ARC 3857C**, IAB 6/20/18, effective 7/25/18]

These rules are intended to implement Iowa Code sections 124.301 through 124.303, 124.306, 155A.4, and 155A.17.

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CHAPTER 18
CENTRALIZED PRESCRIPTION FILLING AND PROCESSING

657—18.1(155A) Purpose and scope. The purpose of this chapter is to provide standards for centralized prescription drug order filling or centralized prescription processing by a pharmacy. Any facility established for the purpose of filling or processing prescription drug orders on behalf of other pharmacies shall be licensed as a pharmacy and shall hold all necessary registrations. A hospital pharmacy may participate in centralized prescription filling only of prescription drug orders for noncontrolled substances pursuant to these rules. A hospital pharmacy may engage in centralized prescription processing pursuant to the requirements of rule 657—7.7(155A). Except as specifically identified in the rules, the requirements of these rules for centralized prescription filling or centralized prescription processing are in addition to the requirements of 657—Chapters 6, 7, and 8, and other rules of the board relating to services provided by pharmacies.

657—18.2(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Central fill pharmacy" means a pharmacy contracting with an originating pharmacy, or having the same owner as an originating pharmacy, that provides centralized prescription drug order filling on behalf of the originating pharmacy pursuant to these rules.

"Centralized prescription drug order filling" or *"centralized filling"* means the filling of a prescription drug order by a pharmacy on behalf of another pharmacy. "Centralized filling" does not include the processing or dispensing of a prescription drug order but may include any of the following filling functions:

1. Receiving prescription drug orders from the originating pharmacy;
2. Interpreting or clarifying prescription drug orders;
3. Entering prescription drug order information into a pharmacy's prescription record system;
4. Selecting, counting, and placing the prescribed drug into an appropriate prescription container;
5. Affixing the prescription label, including any auxiliary labels, to the prescription container;
6. Obtaining refill and substitution authorizations;
7. Verifying all filling processes performed by the central fill pharmacy.

"Centralized prescription drug order processing" or *"centralized processing"* means the processing of a prescription drug order by a pharmacy on behalf of another pharmacy. "Centralized processing" does not include the filling or dispensing of a prescription drug order but may include any of the following processing functions:

1. Interpreting or clarifying prescription drug orders;
2. Entering prescription drug order information into a pharmacy's prescription record system;
3. Interpreting clinical data for prior authorization for dispensing;
4. Performing formulary-directed therapeutic interchange.

"Central processing pharmacy" means a pharmacy contracting with an originating pharmacy, or having the same owner as an originating pharmacy, that provides centralized prescription drug order processing on behalf of the originating pharmacy pursuant to these rules.

"DEA" means the U.S. Department of Justice, Drug Enforcement Administration.

"Dispense" means the delivery of a prescription drug or device to an ultimate user or the ultimate user's agent by or pursuant to the lawful order of a practitioner. "Dispense" includes:

1. Receiving the prescription drug order from the patient, the patient's agent, or the prescriber;
2. Delivering the filled prescription to the patient or the patient's agent;
3. Providing drug information concerning a patient's drug therapy;
4. Providing patient counseling;
5. Providing medication therapy management.

"Hospital" means a facility licensed pursuant to Iowa Code chapter 135B.

"Hospital pharmacy" means and includes a pharmacy licensed by the board and located within any hospital, health system, institution, or establishment which maintains and operates organized facilities

for the diagnosis, care, and treatment of human illnesses to which persons may or may not be admitted for overnight stay at the facility.

"Mail order pharmacy" means a pharmacy located within a United States jurisdiction whose primary business is to dispense a prescription drug or device pursuant to a valid prescription drug order and to deliver the drug or device to a patient, including a patient in this state, via the United States Postal Service, a common carrier, or a delivery service. "Mail order pharmacy" includes a pharmacy that does business via the Internet or other electronic media.

"Medication therapy management" means the review of drug therapy regimens of a patient by a pharmacist for the purpose of evaluating and rendering advice to a practitioner, or for the purpose of evaluating and modifying the drug regimen in accordance with a collaborative drug therapy management protocol pursuant to rule 657—39.13(155A).

"Originating pharmacy" means a pharmacy that receives a prescription drug order from a patient, the patient's agent, or a prescriber, outsources prescription filling or processing functions to another pharmacy, and ultimately dispenses the prescription drug or device to the patient or the patient's agent.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—18.3(155A) General requirements.

18.3(1) *Essential qualifications.* An originating pharmacy may outsource prescription drug filling to a central fill pharmacy or prescription drug order processing to a central processing pharmacy provided the pharmacies:

a. Have the same owner or have entered into a written contract or agreement, which is available for inspection and copying by the board or its authorized agent, that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and

b. Share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to perform the contracted functions.

18.3(2) *Legal compliance.* An originating pharmacy, a central fill pharmacy, and a central processing pharmacy shall comply with all provisions applicable to the pharmacy contained in federal and state laws, rules, and regulations to the extent applicable for the specific filling or processing activity and these rules, including but not limited to the following:

a. Each pharmacy located within Iowa shall maintain Iowa pharmacy licensure and, if the pharmacy dispenses controlled substances, the pharmacy shall maintain DEA and Iowa controlled substances registrations.

b. Each pharmacy located outside Iowa shall maintain Iowa nonresident pharmacy licensure in addition to the licensure requirements of the pharmacy's home state.

c. Each pharmacist providing centralized prescription drug order processing or filling functions as an employee or agent of a central processing or central fill pharmacy located within Iowa shall maintain active licensure to practice pharmacy in Iowa.

d. Pharmacies shall comply with Iowa board rules relating to the duties that must be performed by a pharmacist.

e. Pharmacies shall comply with Iowa requirements for supervision of pharmacy technicians and pharmacy support persons.

18.3(3) *Originating pharmacy responsibility.* Except as specifically provided by this subrule, the originating pharmacy shall be responsible for all dispensing functions as the term "dispense" is defined in rule 657—18.2(155A). An originating pharmacy contracting only for centralized filling shall retain responsibility for all processing functions, and an originating pharmacy contracting only for centralized processing shall retain responsibility for all filling functions.

a. A mail order pharmacy engaged in the centralized filling of prescription drug orders may deliver a filled prescription directly to the patient and shall not be required to return the filled prescription to the originating pharmacy.

b. A central fill or a central processing pharmacy that shares a common central processing unit with the originating pharmacy may perform prospective drug use review (DUR) pursuant to

rule 657—8.21(155A). Only a pharmacist shall perform the DUR, and such review shall not be delegated. The pharmacist performing the DUR shall document in the shared patient record all concerns, recommendations, observations, and comments resulting from that review. The pharmacist at the originating pharmacy shall utilize the DUR notes in counseling the patient pursuant to rule 657—6.14(155A).

18.3(4) *Central fill label requirements.* The label affixed to the prescription container filled by a central fill pharmacy on behalf of an originating pharmacy shall include the following:

a. A unique identifier indicating that the prescription was filled at the central fill pharmacy;

b. Serial number (a unique identification number of the prescription) as assigned by the originating pharmacy;

c. The name, address, and telephone number of the originating pharmacy;

d. The name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner;

e. The name of the prescribing practitioner;

f. The date the prescription is filled by the central fill pharmacy;

g. The directions or instructions for use, including precautions to be observed;

h. Unless otherwise directed by the prescriber, the name, strength, and quantity of the drug dispensed.

(1) If a pharmacist selects an equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label shall identify the generic drug and may identify the brand name drug for which the selection is made, such as "(generic name) Generic for (brand name product)".

(2) If a pharmacist selects a brand name drug product for a generic drug product prescribed by a practitioner, the prescription container label shall identify the brand name drug product dispensed and may identify the generic drug product ordered by the prescriber, such as "(brand name product) for (generic name)";

i. The initials or other unique identification of the pharmacist who performed drug use review.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 3863C**, IAB 6/20/18, effective 7/25/18]

657—18.4 Reserved.

657—18.5(155A) Patient notification and authorization.

18.5(1) *Prior notification and authorization.* A pharmacy that outsources prescription drug order filling or prescription drug order processing to another pharmacy shall, prior to outsourcing a patient's prescription:

a. Notify the patient or the patient's agent that prescription filling or processing may be outsourced to another pharmacy.

b. Provide the name of the pharmacy that will be filling or processing the prescription or, if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may fill or process the prescription, the patient shall be notified of this fact. Notification shall be provided through a notice to the patient or the patient's agent by means of a sign prominently displayed in the originating pharmacy and through written notice provided to the patient or the patient's agent prior to implementation of the program or upon commencement of services to a new patient, as applicable.

c. If a patient provides the originating pharmacy with notification that the patient no longer authorizes the originating pharmacy to outsource the patient's prescription drug orders, the originating pharmacy shall discontinue outsourcing the filling or processing of the patient's prescription drug orders.

18.5(2) *Exception.* The provisions of this rule do not apply to a patient in a facility, such as a hospital or care facility, where Iowa law requires that drugs be administered to the patient by a health care professional.

[**ARC 3863C**, IAB 6/20/18, effective 7/25/18]

657—18.6 to **18.9** Reserved.

657—18.10(155A) Policy and procedures. Pursuant to rule 657—8.3(155A), a policy and procedure manual relating to centralized filling or centralized processing activities shall be maintained at all pharmacies involved in centralized filling or centralized processing and shall be available for inspection and copying by the board or its authorized agent. The manual shall:

1. Outline the responsibilities of each of the pharmacies;
2. Include a list of the names, addresses, telephone numbers, and all license and registration numbers of the pharmacies involved in centralized filling or centralized processing; and
3. Include, but not necessarily be limited to, policies and procedures for:

- Protecting the confidentiality and integrity of patient information;
- Protecting each patient's freedom of choice of pharmacy services;
- Maintaining appropriate records to identify the name, the initials or unique identification code, and the specific activities of each pharmacist or pharmacy technician who performed any centralized filling or centralized processing function; and
- Operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

[**ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 3863C**, IAB 6/20/18, effective 7/25/18]

657—18.11 to **18.14** Reserved.

657—18.15(155A) Records. Central fill or central processing pharmacies shall maintain appropriate records that identify, by prescription drug order, the initials or unique identification code of each pharmacist or pharmacy technician who performs a centralized filling or centralized processing function for a prescription drug order. Originating pharmacies shall maintain appropriate records that identify, by prescription drug order, the initials or unique identification code of the pharmacist who performed drug use review. These records may be maintained separately by each pharmacy or in a common electronic file as long as the data processing system is capable of producing a printout that lists the functions performed by each pharmacy and pharmacist or technician and identifies the pharmacist or technician who performed each function.

[**ARC 3863C**, IAB 6/20/18, effective 7/25/18]

These rules are intended to implement Iowa Code sections 124.301, 124.306, 124.308, 155A.13, and 155A.28.

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CHAPTER 19
NONRESIDENT PHARMACY PRACTICE

657—19.1(155A) Definitions.

"Board" means the Iowa board of pharmacy.

"FDA" means the United States Food and Drug Administration.

"Home state" means the state in which a pharmacy is located.

"Nonresident pharmacy" means a pharmacy, including an Internet-based pharmacy, located outside the state of Iowa that delivers, dispenses, or distributes, by any method, prescription drugs, devices, or pharmacy services to an ultimate user physically located in this state.

"Nonresident pharmacy license" means a pharmacy license issued to a nonresident pharmacy.

"Pharmacy services" includes, but is not limited to, nonproduct services provided by an Iowa-licensed pharmacist or a pharmacist practicing at an Iowa-licensed nonresident pharmacy, such as patient counseling and drug information, pharmaceutical care, and assessment of health risks.

"Registered pharmacist in charge" means the pharmacist in charge at the nonresident pharmacy who is registered with the board and is legally responsible for the operation of the nonresident pharmacy with respect to the provision of prescription drugs, devices, or pharmacy services to patients located in Iowa.
[**ARC 3237C**, IAB 8/2/17, effective 9/6/17]

657—19.2(155A) Nonresident pharmacy license. A nonresident pharmacy shall apply for and obtain, pursuant to provisions of rule 657—8.35(155A), a nonresident pharmacy license from the board prior to providing prescription drugs, devices, or pharmacy services to an ultimate user in this state. All requirements of rule 657—8.35(155A) regarding licensure are applicable to nonresident pharmacies unless otherwise provided in this rule. Any pharmacy that dispenses controlled substances to Iowa residents shall also register pursuant to 657—Chapter 10.

19.2(1) *Inspection requirements.* In lieu of the inspection requirement identified in 657—subrule 8.35(4), a nonresident pharmacy submitting any application for licensure, except when related to a change in location, shall submit with its application and fee an inspection report that satisfies the following requirements:

a. Less than two years have passed since the date of the inspection and the inspection report is the most recent inspection report available that satisfies the requirements of these rules.

b. The inspection occurred while the pharmacy was in operation. An inspection prior to the initial opening of the pharmacy shall not satisfy this requirement.

c. The inspection report addresses all aspects of the pharmacy's business that will be utilized in Iowa.

d. The inspection was performed by or on behalf of the home state licensing authority, if available.

19.2(2) *Qualified inspector.* If the home state licensing authority has not conducted an inspection satisfying the inspection requirements, the nonresident pharmacy shall submit an inspection report issued by one of the following:

a. The verified pharmacy program offered by the National Association of Boards of Pharmacy®.

b. Another qualified entity if the entity is preapproved by the board.

c. An authorized agent of the board. The board may recover from a nonresident pharmacy, prior to the issuance of a nonresident pharmacy license, the costs associated with conducting an inspection.

19.2(3) *Corrective action.* The nonresident pharmacy shall submit evidence of corrective action taken to satisfy any deficiency identified in the inspection report and of compliance with all legal directives of the home state licensing authority.

19.2(4) *Nonresident pharmacy license changes.* A nonresident pharmacy shall submit a completed application and fee pursuant to 657—subrule 8.35(6) except as provided in this rule.

a. Name. A change of the pharmacy name which is provided to patients shall require submission of a pharmacy license application and fee within ten days after issuance by the home state regulatory authority of a license bearing the new name.

b. Location. A change of pharmacy location shall require submission of a pharmacy license application, with the exception of the inspection requirements pursuant to subrule 19.2(1), and fee within ten days after issuance by the home state regulatory authority of a license bearing the new address.

c. Pharmacist in charge. A change in the pharmacist in charge shall require submission of a pharmacy license application and fee within ten days of the identification of a permanent pharmacist in charge pursuant to 657—subrule 8.35(6). If a temporary pharmacist in charge is identified, written notification shall be provided to the board pursuant to 657—paragraph 8.35(6)*"d."* The temporary pharmacist in charge shall not be required to be registered pursuant to rule 657—19.3(155A).

19.2(5) *Closing pharmacy or discontinuation of services.* If a nonresident pharmacy is closing, the pharmacy shall comply with the requirements in 657—subrule 8.35(7). If a nonresident pharmacy is discontinuing provision of pharmacy services to Iowa, but not closing, the pharmacy shall comply with the requirements in the introductory paragraph of 657—subrule 8.35(7) as it relates to transferring patient records to another Iowa-licensed pharmacy and 657—paragraphs 8.35(7)*"b"* and *"d."* The notice requirements of this rule shall not apply in the case of a board-approved emergency or unforeseeable closure, including but not limited to emergency board action, foreclosure, fire, or natural disaster. The nonresident pharmacy shall return to the board the nonresident pharmacy license certificate and, if registered, the Iowa controlled substances Act registration certificate within ten days following the closure or discontinuation of service.

[**ARC 3237C**, IAB 8/2/17, effective 9/6/17; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—19.3(155A) Registered pharmacist in charge. The permanent pharmacist in charge of the nonresident pharmacy shall be designated as such on the nonresident pharmacy license application. Beginning January 1, 2018, the pharmacist in charge shall be registered with the board. The pharmacist in charge shall submit a completed application and a registration fee of $75. The registration shall expire on December 31 following the date of issuance of the registration. An initial registration issued between November 1 and December 31 shall not require renewal until the following calendar year.

19.3(1) *Registered pharmacist in charge application.* The pharmacist in charge of an Iowa-licensed nonresident pharmacy who is not currently actively licensed to practice pharmacy in Iowa shall be registered with the board. The pharmacist in charge shall submit to the board an application that includes the following information:

a. The pharmacist's name and contact information.

b. The pharmacist's license or registration number in the state in which the nonresident pharmacy is located.

c. The pharmacist's current place of employment.

d. Verification that the pharmacist's license in the state in which the nonresident pharmacy is located is current and in good standing.

e. Documentation that the applicant has successfully completed the most current educational training module approved by the board regarding the board's rules as they relate to nonresident pharmacy practice.

f. Criminal and disciplinary history information.

19.3(2) *Registration changes and voluntary cancellation.* A registered pharmacist in charge of a nonresident pharmacy shall notify the board in writing within ten days of any change of information included on the registration application, including the pharmacist's name, contact information, home state license or registration information or status, and place of employment. If a registered pharmacist in charge ceases to be the pharmacist in charge of an Iowa-licensed nonresident pharmacy, the pharmacist may voluntarily request that the registration be canceled and the pharmacist shall not be subject to the inactive registration and reactivation procedure as identified in paragraph 19.3(3)*"b."*

19.3(3) *Registration renewal.* The registration of a pharmacist in charge at a nonresident pharmacy shall be renewed or canceled prior to January 1 of each year. The pharmacist in charge shall submit a completed application and fee as required in this rule.

a. Delinquent registration grace period. If the registration of a pharmacist in charge has not been renewed or canceled prior to expiration, but the pharmacist is in the process of renewing the registration, the registration becomes delinquent on January 1. A pharmacist in charge who submits a completed registration renewal application, application fee, and late penalty fee of $75 postmarked or delivered to the board office by January 31 shall not be subject to disciplinary action for continuing to serve as pharmacist in charge without a current registration in the month of January.

b. Delinquent license reactivation beyond grace period. If the registration of a pharmacist in charge has not been renewed prior to the expiration of the one-month grace period identified in paragraph 19.3(3)*"a,"* the nonresident pharmacy may not continue to provide services to Iowa patients. A nonresident pharmacy that continues to provide services to Iowa patients without a currently registered pharmacist in charge may be subject to disciplinary sanctions. A pharmacist in charge without a current registration may apply for reactivation by submitting a registration application for reactivation and a $300 reactivation fee. As part of the reactivation application, the nonresident pharmacy shall disclose the services, if any, that were provided to Iowa patients while the registration of the pharmacist in charge was delinquent.

[**ARC 3237C**, IAB 8/2/17, effective 9/6/17]

657—19.4(124,155A) Applicability of board rules. A nonresident pharmacy shall comply with all requirements of this chapter, 657—Chapter 8, and any other board rules relating to the services that are provided by the pharmacy to patients in Iowa.

19.4(1) *Type of pharmacy practice.* A nonresident pharmacy, based on the principal type of pharmacy practice, shall comply with board rules as follows:

a. A "general pharmacy" as described in rule 657—6.1(155A) shall comply with all requirements of 657—Chapter 6.

b. A "hospital pharmacy" as described in rule 657—7.1(155A), excepting licensure pursuant to Iowa Code chapter 135B, shall comply with all requirements of 657—Chapter 7.

c. A "limited use pharmacy" as described in 657—subrule 8.35(1) shall comply with all requirements of the limited use pharmacy practice.

d. An "outsourcing facility" as described in rule 657—41.2(155A) shall comply with all requirements of 657—Chapters 41 and 20.

19.4(2) *Controlled substances.* A nonresident pharmacy providing prescription drugs identified as controlled substances under Iowa Code chapter 124 shall register with the board and comply with all requirements of 657—Chapter 10.

19.4(3) *Compounding.* A nonresident pharmacy engaged in the compounding of drug products as defined in rule 657—20.2(124,126,155A) shall comply with all requirements of 657—Chapter 20.

19.4(4) *Long-term care services.* A nonresident pharmacy providing services to Iowa patients in a long-term care facility as defined in 657—Chapter 23 shall comply with all requirements of 657—Chapters 22 and 23.

19.4(5) *Electronic data.* A nonresident pharmacy utilizing any electronic data processing or transmission devices or services shall comply with all requirements of 657—Chapter 21.

[**ARC 3237C**, IAB 8/2/17, effective 9/6/17; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—19.5 and **19.6** Reserved.

657—19.7(155A) Confidential data. Pursuant to rule 657—8.3(155A), each nonresident pharmacy shall have policies and procedures to ensure patient confidentiality and to protect patient identity and patient-specific information from inappropriate or nonessential access, use, or distribution pursuant to the requirements of rule 657—8.16(124,155A).

[**ARC 3237C**, IAB 8/2/17, effective 9/6/17]

657—19.8(124,155A) Storage and shipment of drugs and devices. Pursuant to rule 657—8.3(155A), each nonresident pharmacy shall have policies and procedures to ensure compliance with rules 657—8.7(155A) and 657—8.15(155A). Policies and procedures shall provide for the shipment of

controlled substances via a secure and traceable method, and all records of such shipment and delivery to Iowa patients shall be maintained for a minimum of two years from the date of delivery.
[**ARC 3237C**, IAB 8/2/17, effective 9/6/17]

657—19.9(155A) Patient record system, prospective drug use review, and patient counseling.

19.9(1) *Patient record system.* A patient record system shall be maintained pursuant to rule 657—6.13(155A) for Iowa patients for whom prescription drug orders are dispensed.

19.9(2) *Prospective drug use review.* A pharmacist shall, pursuant to the requirements of rule 657—8.21(155A), review the patient record and each prescription drug order before dispensing.

19.9(3) *Patient counseling.* Pursuant to rule 657—8.3(155A), each nonresident pharmacy shall have policies and procedures to ensure that Iowa patients receive appropriate counseling pursuant to the requirements of rule 657—6.14(155A).
[**ARC 3237C**, IAB 8/2/17, effective 9/6/17]

657—19.10(155A) Reporting discipline and criminal convictions. A nonresident pharmacy or registered pharmacist in charge shall provide notice to the board of any discipline imposed by any licensing authority on any license or registration held by the pharmacy or pharmacist in charge no later than 30 days after the final action. Discipline may include, but is not limited to, fine or civil penalty, citation or reprimand, probationary period, suspension, revocation, and voluntary surrender. A nonresident pharmacy or pharmacist in charge shall provide written notice to the board of any criminal conviction of the pharmacy, of any pharmacy owner, or of the pharmacist in charge that is related to prescription drugs or related to the operation of the pharmacy no later than 30 days after the conviction. The term "criminal conviction" includes instances when the judgment of conviction or sentence is deferred.
[**ARC 3237C**, IAB 8/2/17, effective 9/6/17]

657—19.11(155A) Discipline. Pursuant to 657—Chapter 36, the board may fine, suspend, revoke, or impose other disciplinary sanctions on a nonresident pharmacy license or pharmacist in charge registration for any of the following:

1. Any violation of the Federal Food, Drug, and Cosmetic Act or federal regulations promulgated under the Act. A warning letter issued by the FDA shall be conclusive evidence of a violation.
2. Any conviction of a crime related to prescription drugs or the practice of pharmacy committed by the nonresident pharmacy, pharmacist in charge, or individual owner, or if the pharmacy is an association, joint stock company, partnership, or corporation, by any managing officer.
3. Refusal of access to the pharmacy or pharmacy records to an agent of the board for the purpose of conducting an inspection or investigation.
4. Employing or continuing to employ a pharmacist in charge without a current and active registration pursuant to rule 657—19.3(155A).
5. Any violation of Iowa Code chapter 124, 124B, 126, 155A, or 205 or any rule of the board.

[**ARC 3237C**, IAB 8/2/17, effective 9/6/17; **ARC 3857C**, IAB 6/20/18, effective 7/25/18]

These rules are intended to implement Iowa Code sections 124.301, 124.306, 155A.13, 155A.13A, 155A.13C, 155A.19, and 155A.35.

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CHAPTER 23
CARE FACILITY PHARMACY PRACTICE

657—23.1(155A) Purpose and scope. The purpose of this chapter is to identify the minimum standards for licensed pharmacies in this state providing pharmacy services to care facilities.
[**ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.2(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Authorized collection program" means a program administered by a registrant that has modified its registration with DEA to collect controlled substances for the purpose of disposal. Federal regulations for such programs can be found at www.deadiversion.usdoj.gov/drug_disposal.

"Care facility" or *"facility"* means:

1. A facility licensed by the Iowa department of inspections and appeals under Iowa Code chapter 135C or 135H;
2. A hospital-based long-term care unit certified under 42 CFR, Part 483, Subpart B;
3. An inpatient hospice certified under 42 CFR, Part 418;
4. A group living facility wherein health care-related services are provided by the facility; or
5. A health care facility registered with the board under Iowa Code chapter 124.

"Care facility pharmacy" or *"provider pharmacy"* means a pharmacy that provides pharmacy services to a care facility.

"Consultant pharmacist" in a care facility means an Iowa-licensed pharmacist who is responsible for developing, coordinating, and supervising pharmaceutical services in a care facility on a regularly scheduled basis.

"DEA" means the United States Department of Justice, Drug Enforcement Administration.

"Medication order," as used in these rules, means an order from a practitioner or the practitioner's authorized agent for administration of a drug or device. For purposes of this chapter, "medication order" includes a prescription.

"Provider pharmacist" means a pharmacist licensed to engage in the practice of pharmacy who is employed by or contracted to a care facility pharmacy or a provider pharmacy and who is responsible for supervising the accurate dispensing and proper delivery of drugs and devices to a care facility located within this state. These services shall include, at a minimum, proper medication labeling, storage, transport, record keeping, and prospective drug utilization review in compliance with all federal and state laws and regulations.

"Unit dose dispensing system" means a drug distribution system utilizing unit dose packaging.
[**ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.3(124,155A) Freedom of choice. Pursuant to 657—subrule 8.11(2), no pharmacist or pharmacy shall participate in any agreement or plan that infringes on any resident's right to freedom of choice as described in rules of the department of inspections and appeals.
[**ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.4(124,155A) Responsibilities. The pharmacist in charge and staff pharmacists in any pharmacy providing pharmaceutical services to care facility patients shall share responsibility for:

1. Dispensing drugs pursuant to a medication order for an individual resident that are properly labeled and packaged in a manner consistent with the facility's established drug delivery system and in compliance with applicable board rules for the drug delivery system.
2. Affixing labels to each container of drugs for residents in care facilities, in compliance with 657—Chapter 22 or rule 657—6.10(126,155A), 657—23.13(124,155A), or 657—23.14(124,155A).
3. Maintaining records as required by law and maintaining accurate control over and accountability for all drugs and prescription devices.
4. Complying with a drug recall procedure, established pursuant to rule 657—8.3(155A), that protects the health and safety of residents.
5. Providing 24-hour emergency service either directly or by contract with another pharmacy.

6. Conducting prospective drug use review pursuant to rule 657—8.21(155A) and subrule 23.5(1).

7. Providing sufficient and accurate information to facility staff regarding the appropriate administration and use of all dispensed drugs and devices.

8. Communicating with the consultant pharmacist and the facility staff regarding concerns and resolution thereof.

[**ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.5(124,155A) Emergency drugs. A supply of emergency drugs may be provided by one or more pharmacies to the facility pursuant to rule 657—22.7(124,155A).

23.5(1) *Emergency medication order—pharmacist review.* When an emergency drug is provided pursuant to rule 657—22.7(124,155A), the medication order shall be reviewed by the resident's dispensing pharmacist prior to the administration of a second dose.

23.5(2) *Other emergency drugs and devices.* In addition to emergency drug supplies, a care facility may maintain a stock of intravenous fluids, irrigation fluids, heparin flush kits, medicinal gases, sterile water and saline, and prescription devices. Such stock shall be limited to a listing to be determined by the provider pharmacist in consultation with the consultant pharmacist and the medical director and director of nursing of the facility.

[**ARC 0749C**, IAB 5/29/13, effective 7/3/13; **ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.6(124,155A) Space, equipment, and supplies. Rescinded **ARC 3859C**, IAB 6/20/18, effective 7/25/18.

657—23.7(124,155A) Policies and procedures. Pursuant to rule 657—8.3(155A), each pharmacy shall have policies and procedures related to all aspects of the pharmacy's packaging and dispensing responsibilities to the residents of a care facility. The policies and procedures shall be maintained at the provider pharmacy and shall be available to the facility and the consultant pharmacist. Policies and procedures shall include, at a minimum:

1. Methods used to dispense and deliver drugs and devices to the facility in a timely fashion.

2. Proper notification to the facility when a drug or device is not readily available.

3. Proper labeling requirements to meet the needs of the facility and which are consistent with state and federal laws and regulations.

4. Appropriate drug destruction or return of unused drugs, or both, consistent with state and federal laws and regulations.

5. An automatic stop order policy to ensure that drug orders are not continued inappropriately.

6. Methods to ensure that all discontinued, outdated, deteriorated, or improperly labeled drugs and all containers with worn, illegible or missing labels are disposed of so as to render them unusable and protected from unauthorized possession or use.

[**ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.8 Reserved.

657—23.9(124,155A) Medication orders. Drugs and prescription devices may be dispensed only upon orders of an authorized prescriber or authorized pharmacist as part of a collaborative drug therapy management protocol pursuant to rule 657—39.13(155A).

23.9(1) *Requirements for noncontrolled substances.* New medication orders transmitted to the pharmacy for noncontrolled substances shall, at a minimum, contain resident name, drug name and strength, directions for use, date of order, and name of prescriber.

23.9(2) *Requirements for controlled substances.* New medication orders transmitted to the pharmacy for controlled substances, including Schedule II controlled substances, shall be in compliance with 657—Chapter 10, 657—Chapter 21, and federal regulations.

23.9(3) *Who may transmit medication orders.* An authorized prescriber or prescriber's agent may transmit to the pharmacy a medication order lawfully ordered by an authorized prescriber. An order transmitted by the prescriber's agent shall include the agent's first and last names and title. Specifically

for the transmission of a controlled substance prescription, a member of the care facility staff is an agent of the prescriber only if the prescriber maintains an office in the facility or there exists an agent agreement between the prescriber and the care facility staff member.
[**ARC 9912B**, IAB 12/14/11, effective 1/18/12; **ARC 2197C**, IAB 10/14/15, effective 11/18/15; **ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.10(124,155A) Stop orders. Rescinded **ARC 3859C**, IAB 6/20/18, effective 7/25/18.

657—23.11(124,155A) Drugs dispensed—general requirements.

23.11(1) *Labeling.* All prescription containers, other than those dispensed pursuant to 657—Chapter 22, rule 657—23.13(124,155A), or rule 657—23.14(124,155A), shall be properly labeled in accordance with 657—subrule 6.10(1).

a. If a label change is required to reflect a change in directions, the pharmacist shall be responsible for affixing the correct label to the container. Care facility personnel shall not be directed by the pharmacy to affix such a label to the drug container.

b. Direction change labels that notify care facility personnel that a change in directions for the drug has taken place may be used and affixed to the container by facility personnel so as not to deface the original label.

23.11(2) *Medication order required.* Dispensing of all drugs to the facility shall be pursuant to a medication order for an individual resident except as provided in rules 657—23.5(124,155A) and 657—23.14(124,155A).

23.11(3) *Prescription containers.* All prescription containers utilized for dispensing drugs to a care facility shall meet minimum requirements as established by the United States Pharmacopoeia and 657—Chapter 22. When applicable, light-resistant packaging shall be used.

23.11(4) *Floor stock.* Prescription drugs, as defined by Iowa Code section 155A.3(38), shall not be floor-stocked in a care facility except as provided in this subrule or in subrule 23.5(2). Bulk supplies of nonprescription drugs may be maintained as provided in subrule 23.13(3). Any pharmacy that utilizes a floor stock distribution system pursuant to this subrule shall develop and implement procedures to accurately establish proof of use of prescription drugs and shall maintain a perpetual inventory, whether by electronic or manual means, of all prescription drugs so dispensed. A floor stock distribution system for prescription drugs may be permitted only under the following circumstances:

a. A licensed pharmacy under the direct supervision and control of a pharmacist is established in the facility; or

b. The facility and the hospital wherein the licensed pharmacy is located are both licensed under Iowa Code chapter 135B with a single hospital license.
[**ARC 2408C**, IAB 2/17/16, effective 3/23/16; **ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.12 Reserved.

657—23.13(124,155A) Labeling drugs under special circumstances.

23.13(1) *Drug products of insufficient size to accommodate pharmacy labeling.* Drug products, such as insulin, ophthalmics, otic preparations, and injectables, that are of insufficient size to accommodate a full pharmacy label shall be dispensed with a label affixed to the immediate container showing at least the resident's name and location.

23.13(2) *Legend solutions—irrigation and infusion.* Legend irrigation solutions and infusion solutions supplied by a pharmacy may be stored in the locked medication area of a care facility provided that:

a. The facility uses the solution only within the confines of the facility and under the orders of an authorized prescriber;

b. Upon use, the container is identified by resident name and is used exclusively for that resident;

c. The container is dated and initialed upon opening.

d. The solution is stored appropriately after opening according to facility policy and manufacturer labeling.

23.13(3) *Floor-stocked, nonprescription drug containers.* All nonprescription drugs for use within the facility shall be in appropriate containers and adequately labeled to identify, at a minimum, drug name and manufacturer, strength, lot number, and expiration date.

23.13(4) *Leave meds.* Labeling of prescription drugs for residents on leave from the facility for a period in excess of 24 hours shall comply with 657—subrule 6.10(1). The dispensing pharmacist shall be responsible for packaging and labeling leave meds in compliance with this subrule.

23.13(5) *Discharge meds.* Drugs authorized for a resident being discharged from the facility shall be labeled in compliance with 657—subrule 6.10(1) before the resident removes those drugs from the facility premises. The dispensing pharmacist shall be responsible for packaging and labeling discharge meds in compliance with this subrule.

[**ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.14(124,155A) Provision of drugs to a facility for immunization or screening programs. A pharmacy may provide drugs to be used in the care facility for a health immunization or ongoing screening program, such as influenza vaccine, tuberculin skin test, or hepatitis-B.

23.14(1) *Labeling.* The pharmacy label shall be affixed so as not to obscure the manufacturer's label and shall include the following information.

a. Identification of pharmacy;
b. Name of facility;
c. Name of biological or drug;
d. Route of administration when necessary for clarification;
e. Strength of biological or drug;
f. Auxiliary labels as needed;
g. Date dispensed.

23.14(2) *Influenza and pneumococcal vaccines.* A patient-specific medication order shall not be required prior to administration to an adult patient of influenza or pneumococcal vaccines pursuant to physician-approved facility policy and after the patient has been assessed for contraindications.

23.14(3) *Notification.* The facility shall submit to the provider pharmacy a listing of those residents or staff members who have been immunized utilizing vaccine from each vial supplied by the provider pharmacy.

[**ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.15(124,155A) Return and reuse of drugs and devices. A pharmacy shall not accept from a patient or facility for reuse or resale any drug or device unless, in the professional judgment of the pharmacist, the integrity of the drug or device has not in any way been compromised. Under no circumstances shall a pharmacist accept from a patient or facility any controlled substances except for reuse by the same patient. Prescription drugs, excluding controlled substances, dispensed in a unit dose dispensing system pursuant to 657—Chapter 22 may, however, be returned and reused as authorized in 657—subrule 22.1(6). No items of a personal contact nature which have been removed from the original package or container after dispensing shall be accepted for return, exchanged, or resold by any pharmacist.

[**ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.16(124,155A) Destruction of outdated and improperly labeled drugs. Rescinded **ARC 3859C**, IAB 6/20/18, effective 7/25/18.

657—23.17(124,155A) Accountability of controlled substances. Use of Schedule II controlled substances shall be documented. A committee or representative of the facility may also require that Schedule III, IV, or V controlled substances or any other drugs be accounted for on proof-of-use forms. Documentation shall include at a minimum:

1. Name of drug;
2. Dose;
3. Name of ordering prescriber;

4. Name of resident;
5. Date and time of administration to resident;
6. Identification of individual administering;
7. Documentation of destruction, return to the pharmacy, or other disposition of all unused portions of single doses including the signatures of two individuals, at least one of whom is a licensed health care professional.

[**ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.18(124,155A) Schedule II orders. Rescinded **ARC 3859C**, IAB 6/20/18, effective 7/25/18.

657—23.19(124,155A) Dispensing Schedule II controlled substances. A pharmacy that dispenses Schedule II controlled substances shall advise facility personnel that federal and state laws and regulations governing such drugs require that accurate records be kept of their administration or their ultimate disposition in compliance with rule 657—23.17(124,155A). The pharmacy shall further advise facilities that stored Schedule II substances shall be double-locked in accordance with rules of the Iowa department of inspections and appeals. The requirement for double-locking Schedule II controlled substances shall not apply to periods during which drugs are being administered to residents; however, these substances shall be secured during such administration periods.

657—23.20(124,155A) Partial filling of Schedule II controlled substances. A medication order for a Schedule II controlled substance for a resident in a long-term care facility (LTCF) may be filled in partial quantities to include individual dosage units. The pharmacist shall record on the written or electronic medication order that the patient is an "LTCF patient." A medication order that is partially filled and does not contain the notation "LTCF patient" shall be deemed to have been filled in violation of the controlled substances Act.

23.20(1) *Partial filling record.* For each partial filling, the dispensing pharmacist shall record on the back of the medication order (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.

23.20(2) *Total dispensed.* The total quantity of Schedule II controlled substances dispensed in all partial fillings shall not exceed the total quantity prescribed.

23.20(3) *Duration.* Schedule II medication orders for residents in a long-term care facility shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of the drug.

23.20(4) *Requirements of computerized system.* Information pertaining to current Schedule II medication orders for residents in a long-term care facility may be maintained in a computerized system if this system has the capability to permit:

a. Output (display and printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of resident, address of the long-term care facility, identification of the drug authorized (to include dosage form, strength and quantity), listing of the partial fillings that have been dispensed under each medication order, and the information required in this rule.

b. Immediate (real-time) updating of the medication order record each time a partial filling of the medication order is conducted.

c. Retrieval of partially filled Schedule II medication order information as required in rule 657—21.4(124,155A).

[**ARC 9912B**, IAB 12/14/11, effective 1/18/12]

657—23.21(124,155A) Disposal of previously dispensed controlled substances. Controlled substances dispensed to a resident in a care facility and subsequently requiring disposal due to discontinuance of the drug, death of the resident, or other reasons necessitating disposal shall be disposed of by one of the following methods. Controlled substances shall not be returned to a pharmacy for disposal.

23.21(1) *Disposal in the facility.* A licensed health care professional (pharmacist, registered nurse, licensed practical nurse) may dispose of controlled substances in witness of one other responsible adult. The professional disposing of the drug shall prepare and maintain a readily retrievable record of the disposition which shall be clearly marked to indicate the disposition of resident drugs. The record shall include, at a minimum, the following:

a. Resident name and unique identification or number assigned by the dispensing pharmacy to the prescription;

b. The name, strength, and dosage form of the substance;

c. The quantity disposed of;

d. The date the substance is disposed of;

e. The signature or uniquely identifying initials or other unique identification of the professional and the witness;

f. The name and address of the dispensing pharmacy or the dispensing practitioner.

23.21(2) *Authorized collection program within a facility.* Pharmacies registered with DEA as authorized collectors may install and manage a collection receptacle in a care facility for the purpose of disposal of unwanted medications, including prescription drugs and controlled substances, pursuant to federal regulations.

[**ARC 0749C**, IAB 5/29/13, effective 7/3/13; **ARC 2408C**, IAB 2/17/16, effective 3/23/16; **ARC 3859C**, IAB 6/20/18, effective 7/25/18]

These rules are intended to implement Iowa Code sections 124.301, 124.306, 124.308, 155A.2, 155A.13, 155A.15, 155A.21, 155A.27, 155A.28, 155A.33, 155A.35, and 155A.36.

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CHAPTER 38
Reserved

CHAPTER 39
EXPANDED PRACTICE STANDARDS

657—39.1(155A) Purpose and scope. The purpose of this chapter is to establish the minimum standards for the programs and activities identified in this chapter. These rules shall apply to all licensed pharmacists, other registered pharmacy personnel, and all pharmacies, including owners, engaged in the state of Iowa in the programs and activities identified in this chapter. These rules are in addition to rules of the board relating to the practice of pharmacy unless otherwise indicated by rule.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—39.2 and **39.3** Reserved.

657—39.4(155A) Pharmaceutical care. Pharmaceutical care is a comprehensive, patient-centered, outcomes-oriented pharmacy practice in which the pharmacist accepts responsibility for assisting the prescriber and the patient in optimizing the patient's drug therapy plan and works to promote health, to prevent disease, and to optimize drug therapy. Pharmaceutical care does not include the prescribing of drugs without the consent of the prescriber.

39.4(1) *Drug therapy problems.* In providing pharmaceutical care, the pharmacist shall strive to identify, resolve, and prevent drug therapy problems.

39.4(2) *Drug therapy plan.* In providing pharmaceutical care, the pharmacist shall access and evaluate patient-specific information, identify drug therapy problems, and utilize that information in a documented plan of therapy that assists the patient or the patient's caregiver in achieving optimal drug therapy. In concert with the patient, the patient's prescribing practitioner, and the patient's other health care providers, the pharmacist shall assess, monitor, and suggest modifications of the drug therapy plan as appropriate.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—39.5 and **39.6** Reserved.

657—39.7(135,147A) Opioid antagonist dispensing by pharmacist—standing order. An authorized pharmacist may dispense an opioid antagonist pursuant to a standing order established by the department, which standing order can be found via the board's website, or pursuant to a standing order authorized by an individual licensed health care professional in compliance with the requirements of this rule. An authorized pharmacist may only delegate the dispensing of an opioid antagonist to an authorized pharmacist-intern under the direct supervision of an authorized pharmacist. Nothing in this rule prohibits a prescriber or facility from establishing and implementing standing orders or protocols under the authority granted to the prescriber or facility.

39.7(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"Authorized pharmacist" means an Iowa-licensed pharmacist who has completed the training requirements of this rule. "Authorized pharmacist" also includes an Iowa-registered pharmacist-intern who has completed the training requirements of this rule and is working under the direct supervision of an authorized Iowa-licensed pharmacist.

"Department" means the Iowa department of public health.

"First responder" means an emergency medical care provider, a registered nurse staffing an authorized service program under Iowa Code section 147A.12, a physician assistant staffing an authorized service program under Iowa Code section 147A.13, a firefighter, or a peace officer as defined in Iowa Code section 801.4 who is trained and authorized to administer an opioid antagonist.

"Licensed health care professional" means a person licensed under Iowa Code chapter 148 to practice medicine and surgery or osteopathic medicine and surgery, an advanced registered nurse practitioner licensed under Iowa Code chapter 152 or 152E and registered with the board of nursing, or a physician assistant licensed to practice under the supervision of a physician as authorized in Iowa Code chapters 147 and 148C.

"Opioid antagonist" means the same as defined in Iowa Code section 147A.1.

"Opioid-related overdose" means the same as defined in Iowa Code section 147A.1.

"Person in a position to assist" means a family member, friend, caregiver, health care provider, employee of a substance abuse treatment facility, or other person who may be in a position to render aid to a person at risk of experiencing an opioid-related overdose.

"Recipient" means an individual at risk of an opioid-related overdose or a person in a position to assist an individual at risk of an opioid-related overdose.

"Standing order" means a preauthorized medication order with specific instructions from the licensed health care professional to dispense a medication under clearly defined circumstances.

39.7(2) *Authorized pharmacist training.* An authorized pharmacist shall document successful completion of an ACPE-approved continuing education program of at least one-hour duration related to opioid antagonist utilization prior to dispensing opioid antagonists pursuant to a standing order.

39.7(3) *Additional supply.* Notwithstanding a standing order to the contrary, an authorized pharmacist shall only dispense an opioid antagonist after completing an eligibility assessment and providing training and education to the recipient.

39.7(4) *Assessment.* An authorized pharmacist shall assess an individual for eligibility to receive an opioid antagonist pursuant to a standing order. In addition to the criteria identified in a standing order, an authorized pharmacist shall also take into consideration the following criteria to determine the eligibility of the recipient to receive and possess an opioid antagonist:

a. The person at risk of an opioid-related overdose for which the opioid antagonist is intended to be administered has no known sensitivity or allergy to naloxone, unless the person at risk is not known to the recipient, including but not limited to a first responder or member of law enforcement.

b. The recipient is oriented to person, place, and time and able to understand and learn the essential components of opioid-related overdose, appropriate response, and opioid antagonist administration.

39.7(5) *Recipient training and education.* Upon assessment and determination that an individual is eligible to receive and possess an opioid antagonist pursuant to a standing order, an authorized pharmacist shall, prior to dispensing an opioid antagonist pursuant to a standing order, provide training and education to the recipient including, but not limited to, the information identified in this subrule. An authorized pharmacist shall require the recipient to attest that, if the product will be accessible to any other individual for administration, the recipient will make available to such individual all received training and education materials. An authorized pharmacist may provide to the recipient written materials that include, but may not be limited to, the information identified in this subrule, but the written materials shall not be in lieu of direct pharmacist consultation with the recipient.

a. The signs and symptoms of opioid-related overdose as described in the standing order.

b. The importance of calling 911 as soon as possible and the potential need for rescue breathing.

c. The appropriate use and directions for administration of the opioid antagonist to be dispensed pursuant to the standing order.

d. Adverse reactions of the opioid antagonist as well as reactions resulting from opioid withdrawal following administration.

e. The proper storage conditions, including temperature excursions, of the opioid antagonist being dispensed.

f. The expiration date of the opioid antagonist being dispensed and the appropriate disposal of the opioid antagonist upon expiration.

g. The prohibition of the recipient from further distributing the opioid antagonist to another individual, unless that individual has received appropriate training and education.

h. Information about substance abuse or behavioral health treatment programs.

39.7(6) *Labeling.* Upon the determination that a recipient is eligible to receive and possess an opioid antagonist, an authorized pharmacist shall label the product pursuant to rule 657—6.10(126,155A) and 657—subrule 8.19(8). An authorized pharmacist shall ensure that the labeling does not render the expiration date of the product illegible. The medication shall be dispensed in the name of the eligible recipient.

39.7(7) *Reporting.* A copy of the assessment form shall be submitted to the department as provided on the assessment form within seven days of the dispensing of the opioid antagonist or within seven days of a denial of eligibility.

39.7(8) *Records.* An authorized pharmacist shall create and maintain an original record of each individual assessment on forms provided by the board, regardless of the eligibility determination following assessment, and dispensing of opioid antagonists pursuant to a standing order. These records shall be available for inspection and copying by the board or its authorized agent for at least two years.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—39.8 and **39.9** Reserved.

657—39.10(155A) Vaccine administration by pharmacists. An authorized pharmacist may administer vaccines pursuant to protocols established by the CDC in compliance with the requirements of this rule. An authorized pharmacist may only delegate the administration of a vaccine to an authorized pharmacist-intern under the direct supervision of the authorized pharmacist.

39.10(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"ACIP" means the CDC Advisory Committee on Immunization Practices.

"ACPE" means the Accreditation Council for Pharmacy Education.

"Authorized pharmacist" means an Iowa-licensed pharmacist who has met the requirements identified in subrule 39.10(2).

"Authorized pharmacist-intern" means an Iowa-registered pharmacist-intern who has met the requirements for an authorized pharmacist identified in paragraphs 39.10(2)*"a"* and *"c."*

"CDC" means the United States Centers for Disease Control and Prevention.

"Immunization" shall have the same meaning as, and shall be interchangeable with, the term "vaccine."

"Protocol" means a standing order for a vaccine to be administered by an authorized pharmacist.

"Vaccine" means a specially prepared antigen administered to a person for the purpose of providing immunity.

39.10(2) *Authorized pharmacist training and continuing education.* An authorized pharmacist shall document successful completion of the requirements in paragraph 39.10(2)*"a"* and shall maintain competency by completing and maintaining documentation of the continuing education requirements in paragraph 39.10(2)*"b."*

a. Initial qualification. An authorized pharmacist shall have successfully completed an organized course of study in a college or school of pharmacy or an ACPE-accredited continuing education program on vaccine administration that:

(1) Requires documentation by the pharmacist of current certification in the American Heart Association or the Red Cross Basic Cardiac Life Support Protocol for health care providers.

(2) Is an evidence-based course that includes study material and hands-on training and techniques for administering vaccines, requires testing with a passing score, complies with current CDC guidelines, and provides instruction and experiential training in the following content areas:

1. Standards for immunization practices;
2. Basic immunology and vaccine protection;
3. Vaccine-preventable diseases;
4. Recommended immunization schedules;
5. Vaccine storage and management;
6. Informed consent;
7. Physiology and techniques for vaccine administration;
8. Pre- and post-vaccine assessment, counseling, and identification of contraindications to the vaccine;
9. Immunization record management; and
10. Management of adverse events, including identification, appropriate response, documentation, and reporting.

b. Continuing education. During any pharmacist license renewal period, an authorized pharmacist who engages in the administration of vaccines shall complete and document at least one hour of continuing education related to vaccines.

c. Certification maintained. During any period within which the pharmacist may engage in the administration of vaccines, the pharmacist shall maintain current certification in the American Heart Association or the Red Cross Basic Cardiac Life Support Protocol for health care providers.

39.10(3) *Protocol requirements.* A pharmacist may administer vaccines pursuant to a protocol based on CDC recommendations. A protocol shall be unique to a pharmacy. The pharmacy shall comply with the parameters of the protocol. The prescriber who signs a protocol shall identify within the protocol, by name or category, those pharmacists or other qualified health professionals that the prescriber is authorizing to administer vaccines pursuant to the protocol. A protocol:

a. Shall be signed by an Iowa-licensed prescriber practicing in Iowa.

b. Shall expire no later than one year from the effective date of the signed protocol.

c. Shall be effective for patients who wish to receive a vaccine administered by an authorized pharmacist, who meet the CDC recommended criteria, and who have no contraindications as published by the CDC.

d. Shall require the authorized pharmacist to notify the prescriber who signed the protocol within 24 hours of a serious complication, and the pharmacist shall submit a Vaccine Advisory Event Reporting System (VAERS) report.

e. Shall specifically indicate whether the authorizing prescriber agrees that the administration of vaccines may be delegated by the authorized pharmacist to an authorized pharmacist-intern under the direct supervision of the authorized pharmacist.

39.10(4) *Influenza and other emergency vaccines.* An authorized pharmacist shall only administer via protocol, to patients six years of age and older, influenza vaccines and other emergency vaccines in response to a public health emergency.

39.10(5) *Other adult vaccines.* An authorized pharmacist shall only administer via protocol, to patients 18 years of age and older, the following vaccines:

a. A vaccine on the ACIP-approved adult vaccination schedule.

b. A vaccine recommended by the CDC for international travel.

39.10(6) *Vaccines administered via prescription.* An authorized pharmacist may administer any vaccine pursuant to a prescription or medication order for an individual patient. In case of a serious complication, the authorized pharmacist shall notify the prescriber who authorized the prescription within 24 hours and shall submit a VAERS report.

39.10(7) *Verification and reporting.* The requirements of this subrule do not apply to influenza and other emergency vaccines administered via protocol pursuant to subrule 39.10(4). An authorized pharmacist shall:

a. Prior to administering a vaccine identified in subrule 39.10(5) or 39.10(6), consult the statewide immunization registry or health information network.

b. Within 30 days following administration of a vaccine identified in subrule 39.10(5) or 39.10(6), report the vaccine administration to the statewide immunization registry or health information network and to the patient's primary health care provider, if known.

[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—39.11 and **39.12** Reserved.

657—39.13(155A) Collaborative drug therapy management. An authorized pharmacist may only perform collaborative drug therapy management pursuant to protocol with an authorized provider pursuant to the requirements of this rule. The authorized provider retains the ultimate responsibility for the care of the patient. The pharmacist is responsible for all aspects of drug therapy management performed by the pharmacist.

39.13(1) *Definitions.* For the purpose of this rule, the following definitions shall apply:

"Authorized pharmacist" means an Iowa-licensed pharmacist whose license is in good standing and who meets the drug therapy management criteria defined in this subrule.

"Authorized provider" means an Iowa-licensed prescribing practitioner who is authorized by the practitioner's professional licensing authority to participate in a collaborative practice agreement with an authorized pharmacist pursuant to these rules and the rules of the practitioner's professional licensing authority. An authorized provider who executes a written protocol with an authorized pharmacist shall supervise the pharmacist's activities involved in the overall management of patients receiving medications or disease management services under the protocol. The authorized provider may delegate only drug therapies that are in areas common to the authorized provider's practice.

"Board" means the board of pharmacy.

"Collaborative drug therapy management" means participation by an authorized pharmacist and an authorized provider in the management of drug therapy pursuant to a written community practice protocol or a written hospital practice protocol.

"Collaborative practice" means that an authorized provider may delegate aspects of drug therapy management for the authorized provider's patients to an authorized pharmacist through a community practice protocol. "Collaborative practice" also means that a P&T committee may authorize hospital pharmacists to perform drug therapy management for inpatients and hospital clinic patients through a hospital practice protocol.

"Community practice protocol" means a written, executed agreement entered into voluntarily between an authorized pharmacist and an authorized provider establishing drug therapy management for one or more of the pharmacist's and authorized provider's patients residing in a community setting. A community practice protocol shall comply with the requirements of subrule 39.13(2).

"Community setting" means a location outside a hospital inpatient, acute care setting or a hospital clinic setting. A community setting may include, but is not limited to, a home, group home, assisted living facility, correctional facility, hospice, or long-term care facility.

"Drug therapy management criteria" means one or more of the following:

1. Graduation from a recognized school or college of pharmacy with a doctor of pharmacy (Pharm.D.) degree;
2. Certification by the Board of Pharmaceutical Specialties (BPS);
3. Certification by the Commission for Certification in Geriatric Pharmacy (CCGP);
4. Successful completion of a National Institute for Standards in Pharmacist Credentialing (NISPC) disease state management examination and credentialing by the NISPC;
5. Successful completion of a pharmacy residency program accredited by the American Society of Health-System Pharmacists (ASHP); or
6. Approval by the board of pharmacy.

"Hospital clinic" means an outpatient care clinic operated and affiliated with a hospital and under the direct authority of the hospital's P&T committee.

"Hospital pharmacist" means an Iowa-licensed pharmacist who meets the requirements for participating in a hospital practice protocol as determined by the hospital's P&T committee.

"Hospital practice protocol" means a written plan, policy, procedure, or agreement that authorizes drug therapy management between hospital pharmacists and authorized providers within a hospital and the hospital's clinics as developed and determined by the hospital's P&T committee. Such a protocol may apply to all pharmacists and authorized providers at a hospital or the hospital's clinics or only to those pharmacists and authorized providers who are specifically recognized. A hospital practice protocol shall comply with the requirements of subrule 39.13(3).

"P&T committee" means a committee of the hospital composed of physicians, pharmacists, and other health professionals that evaluates the clinical use of drugs within the hospital, develops policies for managing drug use and administration in the hospital, and manages the hospital drug formulary system.

"Therapeutic interchange" means an authorized exchange of therapeutic alternate drug products in accordance with a previously established and approved written protocol.

39.13(2) *Community practice protocol.*

a. An authorized pharmacist shall engage in collaborative drug therapy management with an authorized provider only under a written protocol that has been identified by topic. Protocols shall be made available upon request of the board or the licensing board of the authorized provider.

b. The community practice protocol shall include:

(1) The name, signature, date, and contact information for each authorized pharmacist who is a party to the protocol and is eligible to manage the drug therapy of a patient. If more than one authorized pharmacist is a party to the agreement, the pharmacists shall work for a single licensed pharmacy and a principal authorized pharmacist shall be designated in the protocol.

(2) The name, signature, date, and contact information for each authorized provider who may prescribe drugs and is responsible for supervising a patient's drug therapy management. The authorized provider who initiates a protocol shall be considered the main caregiver for the patient respective to that protocol and shall be noted in the protocol as the principal authorized provider.

(3) The name and contact information of the principal authorized provider and the principal authorized pharmacist who are responsible for development, training, administration, and quality assurance of the protocol.

(4) A detailed written protocol pursuant to which the authorized pharmacist will base drug therapy management decisions for patients. The protocol shall authorize one or more of the following:

1. Prescription drug orders. The protocol may authorize therapeutic interchange or modification of drug dosages based on symptoms or laboratory or physical findings defined in the protocol. The protocol shall include information specific to the dosage, frequency, duration, and route of administration of the drug authorized by the patient's authorized provider. The protocol shall not authorize the pharmacist to change a Schedule II drug or to initiate a drug not included in the established protocol.

2. Laboratory tests. The protocol may authorize the pharmacist to obtain or to conduct specific laboratory tests as long as the tests relate directly to the drug therapy management.

3. Physical findings. The protocol may authorize the pharmacist to check certain physical findings, e.g., vital signs, oximetry, or peak flows, that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions, or determine if the patient should be referred back to the patient's authorized provider for follow-up.

4. Patient activities. The protocol may authorize the pharmacist to monitor specific patient activities.

(5) Procedures for securing the patient's written consent. If the patient's consent is not secured by the authorized provider, the authorized pharmacist shall secure such and notify the patient's authorized provider within 24 hours.

(6) Circumstances that shall cause the authorized pharmacist to initiate communication with the authorized provider including but not limited to the need for new prescription orders and reports of the patient's therapeutic response or adverse reaction.

(7) A detailed statement identifying the specific drugs, laboratory tests, and physical findings upon which the authorized pharmacist shall base drug therapy management decisions.

(8) A provision for the collaborative drug therapy management protocol to be reviewed, updated, and reexecuted or discontinued at least every two years.

(9) A description of the method the pharmacist shall use to document the pharmacist's decisions or recommendations for the authorized provider.

(10) A description of the types of reports the authorized pharmacist is to provide to the authorized provider and the schedule by which the pharmacist is to submit these reports. The schedule shall include a time frame within which a pharmacist shall report any adverse reaction to the authorized provider.

(11) A statement of the medication categories and the type of initiation and modification of drug therapy that the provider authorizes the pharmacist to perform.

(12) A description of the procedures or plan that the pharmacist shall follow if the pharmacist modifies a drug therapy.

(13) Procedures for record keeping, record sharing, and long-term record storage.

(14) Procedures to follow in emergency situations.

(15) A statement that prohibits the authorized pharmacist from delegating drug therapy management to anyone other than another authorized pharmacist who has signed the applicable protocol.

(16) A statement that prohibits an authorized provider from delegating collaborative drug therapy management to any unlicensed or licensed person other than another authorized provider or an authorized pharmacist.

(17) A description of the mechanism for the pharmacist and the authorized provider to communicate with each other and for documentation by the pharmacist of the implementation of collaborative drug therapy.

c. Collaborative drug therapy management is valid only when initiated by a written protocol executed by at least one authorized pharmacist and at least one authorized provider.

d. The collaborative drug therapy protocol shall be kept on file in the pharmacy and be made available upon request of the board or the authorized provider's licensing board.

e. An authorized provider may terminate or amend the collaborative drug therapy management protocol with an authorized pharmacist if the authorized provider notifies the authorized pharmacist in writing. Notification shall include the name of the authorized pharmacist, the desired change, and the proposed effective date of the change. Written notification shall be maintained in the pharmacy and be made available upon request of the board or the authorized provider's licensing board.

f. The authorized provider or pharmacist who initiates a protocol with a patient is responsible for securing the patient's written consent to participate in drug therapy management and for transmitting a copy of the consent to the other party within 24 hours. The consent shall indicate which protocol is involved. Any variation in the protocol for a specific patient shall be communicated to the other party at the time of securing the patient's consent. The patient's authorized provider shall maintain the patient consent in the patient's medical record.

39.13(3) *Hospital practice protocol.*

a. A hospital's P&T committee shall determine the scope and extent of collaborative drug therapy management practices that may be conducted by the hospital's pharmacists.

b. Collaborative drug therapy management within a hospital setting or the hospital's clinic setting is valid only when approved by the hospital's P&T committee.

c. The hospital practice protocol shall include:

(1) The names or groups of pharmacists and providers who are authorized by the P&T committee to participate in collaborative drug therapy management.

(2) A plan for development, training, administration, and quality assurance of the protocol.

(3) A detailed written protocol pursuant to which the hospital pharmacist shall base drug therapy management decisions for patients. The protocol shall authorize one or more of the following:

1. Medication orders and prescription drug orders. The protocol may authorize therapeutic interchange or modification of drug dosages based on symptoms or laboratory or physical findings defined in the protocol. The protocol shall include information specific to the dosage, frequency, duration, and route of administration of the drug authorized by the authorized provider. The protocol shall not authorize the hospital pharmacist to change a Schedule II drug or to initiate a drug not included in the established protocol.

2. Laboratory tests. The protocol may authorize the hospital pharmacist to obtain or to conduct specific laboratory tests as long as the tests relate directly to the drug therapy management.

3. Physical findings. The protocol may authorize the hospital pharmacist to check certain physical findings, e.g., vital signs, oximetry, or peak flows, that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions, or determine if the patient should be referred back to the authorized provider for follow-up.

(4) Circumstances that shall cause the hospital pharmacist to initiate communication with the patient's authorized provider including but not limited to the need for new medication orders and prescription drug orders and reports of a patient's therapeutic response or adverse reaction.

(5) A statement of the medication categories and the type of initiation and modification of drug therapy that the P&T committee authorizes the hospital pharmacist to perform.

(6) A description of the procedures or plan that the hospital pharmacist shall follow if the hospital pharmacist modifies a drug therapy.

(7) A description of the mechanism for the hospital pharmacist and the patient's authorized provider to communicate and for the hospital pharmacist to document implementation of the collaborative drug therapy.

[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—39.14 and **39.15** Reserved.

657—39.16(155A) Pharmacy pilot or demonstration research projects. The purpose of this rule is to specify the procedures to be followed in applying for approval of a pilot or demonstration research project for innovative applications in the practice of pharmacy as authorized by 2011 Iowa Acts, chapter 63, section 36, as amended by 2012 Iowa Acts, chapter 1113, section 31, and by 2013 Iowa Acts, chapter 138, section 128. In reviewing projects, the board will consider only projects that expand pharmaceutical care services that contribute to positive patient outcomes. The board will not consider any project intended only to provide a competitive advantage to a single applicant or group of applicants.

39.16(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"Act" means Iowa Code chapter 155A, the Iowa pharmacy practice Act.

"Board" means the Iowa board of pharmacy.

"Practice of pharmacy" means the practice of pharmacy as defined in Iowa Code section 155A.3(34).

"Project" means a pilot or demonstration research project as described in this rule.

39.16(2) *Scope of project.* A project may not expand the definition of the practice of pharmacy. A project may include therapeutic substitution or substitution of medical devices used in patient care if such substitution is included under a collaborative drug therapy management protocol established pursuant to rule 657—39.13(155A).

39.16(3) *Board approval of a project.* Board approval of a project may include the grant of an exception to or a waiver of rules adopted under the Act or under any law relating to the authority of prescription verification and the ability of a pharmacist to provide enhanced patient care in the practice of pharmacy. Project approval, including exception to or waiver of board rules, shall initially be for a specified period of time not exceeding 18 months from commencement of the project. The board may approve the extension or renewal of a project following consideration of a petition that clearly identifies the project, that includes a report similar to the final project report described in paragraph 39.16(6)*"a,"* that describes and explains any proposed changes to the originally approved and implemented project, and that justifies the need for extending or renewing the term of the project.

39.16(4) *Applying for approval of a project.* A person who wishes the board to consider approval of a project shall submit to the board a petition for approval that contains at least the following information:

a. Responsible pharmacist. Name, address, telephone number, and pharmacist license number of each pharmacist responsible for overseeing the project.

b. Location of project. Name, address, and telephone number of each specific location and, if a location is a pharmacy, the pharmacy license number where the proposed project will be conducted.

c. Project summary. A detailed summary of the proposed project that includes at least the following information:

(1) The goals, hypothesis, and objectives of the proposed project.

(2) A full explanation of the project and how it will be conducted.

(3) The time frame for the project including the proposed start date and length of study. The time frame may not exceed 18 months from the proposed start date of the project.

(4) Background information or literature review to support the proposed project.

(5) The rule or rules to be waived in order to complete the project and a request to waive the rule or rules.

(6) Procedures to be used during the project to ensure that the public health and safety are not compromised as a result of the waiver.

39.16(5) *Review and approval or denial of a proposed project.*

a. Staff review. Upon receipt of a petition for approval of a project, board staff shall initially review the petition for completeness and appropriateness. If the petition is incomplete or inappropriate for board consideration, board staff shall return the petition to the requestor with a letter explaining the reason the petition is being returned. A petition that has been returned pursuant to this paragraph may be amended or supplemented as necessary and submitted for reconsideration.

b. Board review. Upon review by the board of a petition for approval of a project, the board shall either approve or deny the petition. If the board approves the petition, the approval:

(1) Shall be specific for the project requested;

(2) Shall approve the project for a specific time period; and

(3) May include conditions or qualifications applicable to the project.

c. Inspection. The project site and project documentation shall be available for inspection and review by the board or its representative at any time during the project review and the approval or denial processes and, if a project is approved, throughout the approved term of the project.

d. Documentation maintained. Project documentation shall be maintained and available for inspection, review, and copying by the board or its representative for at least two years following completion or termination of the project.

39.16(6) *Presentation of reports*. The pharmacist responsible for overseeing a project shall be responsible for submitting to the board any reports required as a condition of a project, including the final project report.

a. Final project report. The final project report shall include a written summary of the results of the project and the conclusions drawn from those results. The final project report shall be submitted to the board within three months after completion or termination of the project.

b. Board review. The board shall receive and review any report regarding the progress of a project and the final project report at a regularly scheduled meeting of the board. The report shall be an item on the open session agenda for the meeting.

[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

These rules are intended to implement Iowa Code sections 135.190, 147.76, 147A.18, 155A.2, 155A.3, 155A.13, 155A.33, and 155A.44 and 2011 Iowa Acts, chapter 63, section 36, as amended by 2012 Iowa Acts, chapter 1113, section 31, and by 2013 Iowa Acts, chapter 138, section 128.

[Filed ARC 3858C (Notice ARC 3509C, IAB 12/20/17), IAB 6/20/18, effective 7/25/18]

CHAPTER 41
OUTSOURCING FACILITIES

657—41.1(155A) Purpose and scope. The purpose of this chapter is to establish the minimum standard of practice for outsourcing facilities that intend to provide compounding services in or into Iowa. The requirements of these rules, in addition to any other board rules applicable to the facility's operation, apply to all Iowa-licensed outsourcing facilities that provide compounded medications in or into Iowa whether pursuant to a patient-specific prescription or not.
[**ARC 3238C**, IAB 8/2/17, effective 9/6/17]

657—41.2(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Board" means the Iowa board of pharmacy.

"FDA" means the United States Food and Drug Administration.

"Home state" means the state in which an outsourcing facility is located.

"Outsourcing facility" or *"facility"* means any compounding facility that is registered as an outsourcing facility, as defined in 21 U.S.C. Section 353b, that distributes sterile compounded human drug products without a patient-specific prescription to an authorized agent or practitioner in this state.
[**ARC 3238C**, IAB 8/2/17, effective 9/6/17]

657—41.3(155A) Outsourcing facility license. Beginning January 1, 2018, an outsourcing facility shall apply for and obtain an outsourcing facility license from the board prior to providing non-patient-specific compounded human drug products in this state. The applicant shall submit a completed application along with an application fee of $400. An outsourcing facility that intends to distribute controlled substances in or into Iowa shall also, prior to distributing such substances in or into Iowa, apply for and obtain an Iowa controlled substances Act registration pursuant to 657—Chapter 10.

41.3(1) *Application requirements.* The application shall require demographic information about the facility; ownership information; the name, signature and home state license number for the supervising pharmacist; an attestation that the supervising pharmacist has read and understands the laws and rules relating to sterile compounding in Iowa; information about the entity's registered agent; criminal and disciplinary history information; and a description of the scope of services to be provided in Iowa. As part of the application process, the applicant shall also:

a. Submit evidence of possession of a valid registration with the FDA as an outsourcing facility.

b. If one or more inspections have been conducted by the FDA in the five-year period immediately preceding the application, submit a copy of any correspondence from the FDA as a result of the inspection, including but not limited to any form 483s, warning letters, or formal responses, and all correspondence from the applicant to the FDA related to such inspections, including but not limited to formal responses and corrective action plans. In addition, the applicant shall submit evidence of correction of all deficiencies discovered in such inspections and evidence of compliance with all directives from the FDA.

c. Submit evidence that the supervising pharmacist, as described in 21 U.S.C. Section 353b(a), holds a valid pharmacist license in the state in which the facility is located and that such license is in good standing.

d. Submit information to facilitate a national criminal history record check.

41.3(2) *Provision of patient-specific prescriptions.* If an outsourcing facility intends to dispense prescription drugs pursuant to patient-specific prescriptions to individual patients in Iowa, the outsourcing facility shall also obtain and maintain a valid Iowa pharmacy license. If the pharmacy is located in Iowa, the pharmacy shall obtain and maintain a valid Iowa pharmacy license pursuant to 657—Chapter 8; if the pharmacy is located outside Iowa, the pharmacy shall, prior to dispensing prescriptions to patients located in Iowa, obtain and maintain a valid Iowa nonresident pharmacy license pursuant to 657—Chapter 19.

41.3(3) *License renewal.* The outsourcing facility license shall be renewed by January 1 of each year. The facility shall submit the license application and fee as provided in this rule. An outsourcing facility may renew its license beginning November 1 prior to license expiration. An initial outsourcing facility

license issued between November 1 and December 31 shall not require renewal until the following calendar year. The fee for license renewal shall be $400.

a. Delinquent license grace period. If an outsourcing facility license has not been renewed or canceled prior to expiration, but the facility is in the process of renewing the license, the license becomes delinquent on January 1. An outsourcing facility that submits a completed license renewal application, application fee, and late penalty fee of $400 postmarked or delivered to the board office by January 31 shall not be subject to disciplinary action for continuing to provide services to Iowa customers in the month of January.

b. Delinquent license reactivation beyond grace period. If an outsourcing facility license has not been renewed prior to the expiration of the one-month grace period identified in paragraph 41.3(3)*"a,"* the facility may not continue to provide services to Iowa customers. An outsourcing facility that continues to provide services to Iowa customers without a current license may be subject to disciplinary sanctions. An outsourcing facility without a current license may apply for reactivation by submitting an application for license reactivation and a $1,600 reactivation fee. As part of the reactivation application, the facility shall disclose the services, if any, that were provided to Iowa customers while the license was delinquent.

41.3(4) *License changes.* If an outsourcing facility has a change of name, ownership, location or supervising pharmacist, the facility shall submit to the board an outsourcing facility license application and applicable fee within ten days of the FDA's issuance of an updated registration. Following processing of the completed license application and fee, the board shall issue a new license certificate that reflects the change or changes.

41.3(5) *License cancellation.* If an outsourcing facility ceases to be registered as an outsourcing facility with the FDA, the facility shall immediately cease distribution of non-patient-specific compounded drug products in or into this state and shall return its Iowa outsourcing facility license to the board within ten days of such occurrence. Upon receipt, the board shall administratively cancel the outsourcing facility license. If an outsourcing facility intends to discontinue business in this state, the facility shall notify the board in writing of its intent at least 30 days in advance of the discontinuation of services and request that the license be administratively canceled. To the extent possible to avoid unnecessary delays in obtaining product for patients, an outsourcing facility that intends to discontinue services in Iowa should provide advance notice to its customers of the date that the outsourcing facility intends to cease distributing products in this state. The notice requirements of this rule shall not apply in the case of a board-approved emergency or unforeseeable closure, including but not limited to emergency board action, foreclosure, fire, or natural disaster.

[**ARC 3238C**, IAB 8/2/17, effective 9/6/17]

657—41.4(155A) Applicability of board rules. An outsourcing facility shall comply with all requirements of this chapter, 657—Chapter 20, and any other board rules relating to the services that are provided to Iowa customers.

41.4(1) *Controlled substances.* An outsourcing facility providing prescription drugs identified as controlled substances under Iowa Code chapter 124 to Iowa customers or patients shall comply with all requirements of 657—Chapter 10.

41.4(2) *Electronic data.* An outsourcing facility utilizing any electronic data processing or transmission devices or services shall comply with all requirements of 657—Chapter 21.

41.4(3) *Patient-specific prescriptions.* An outsourcing facility that also provides patient-specific compounded medications pursuant to a prescription shall comply with all requirements of 657—Chapters 8, 19, and 20.

[**ARC 3238C**, IAB 8/2/17, effective 9/6/17]

657—41.5(155A) Reporting discipline and criminal convictions. An outsourcing facility shall provide written notice to the board of any disciplinary or enforcement action imposed by any licensing or regulatory authority on any license or registration held by the facility. Written notice shall be received no later than 30 days after the final action. Discipline may include, but is not limited to, fine or civil penalty, citation or reprimand, probationary period, suspension, revocation, and voluntary surrender. An

outsourcing facility shall provide written notice to the board of any criminal conviction of the facility or of any owner that is related to the operation of the facility no later than 30 days after the conviction. The term "criminal conviction" includes instances when the judgment of conviction or sentence is deferred.
[**ARC 3238C**, IAB 8/2/17, effective 9/6/17]

657—41.6(155A) Discipline. Pursuant to 657—Chapter 36, the board may fine, suspend, revoke, or impose other disciplinary sanctions on an outsourcing facility license for any of the following:

1. Any violation of the Federal Food, Drug, and Cosmetic Act or federal regulations promulgated under the Act. A warning letter issued by the FDA shall be conclusive evidence of a violation.

2. Any conviction of a crime related to prescription drugs or the practice of pharmacy committed by the outsourcing facility, supervising pharmacist, or individual owner, or if the outsourcing facility is an association, joint stock company, partnership, or corporation, by any managing officer.

3. Refusing access to the outsourcing facility or facility records to an agent of the board for the purpose of conducting an inspection or investigation.

4. Failure to maintain licensure pursuant to 657—Chapter 8 or 657—Chapter 19 when dispensing compounded drugs pursuant to patient-specific prescriptions into the state.

5. Any violation of Iowa Code chapter 155A, 124, 124B, 126, or 205 or any rule of the board, including the disciplinary grounds set forth in 657—Chapter 36.

[**ARC 3238C**, IAB 8/2/17, effective 9/6/17; **ARC 3857C**, IAB 6/20/18, effective 7/25/18]

These rules are intended to implement Iowa Code sections 124.301 and 155A.13C.

[Filed ARC 3238C (Notice ARC 3038C, IAB 4/26/17), IAB 8/2/17, effective 9/6/17]
[Filed ARC 3857C (Notice ARC 3506C, IAB 12/20/17), IAB 6/20/18, effective 7/25/18]

LABOR SERVICES DIVISION[875]

[Prior to 11/19/97, see Labor Services Division[347]]

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CHAPTER 66
WAIVERS OR VARIANCES FROM ADMINISTRATIVE RULES BY THE ELEVATOR SAFETY BOARD

875—66.1(17A,89A) Waivers of rules. This chapter outlines generally applicable standards and a uniform process for the granting of individual waivers from rules adopted by the board. To the extent another more specific provision of law governs the issuance of a waiver from a particular rule, the more specific provision shall supersede this chapter with respect to any waiver from that rule.

875—66.2(17A,89A) Applicability of rule. The board may grant a waiver from a rule only if the board has jurisdiction over the rule and the requested waiver is consistent with applicable statutes, constitutional provisions, or other provisions of law. The board may not waive requirements created or duties imposed by statute.

875—66.3(17A,89A) Criteria for waiver or variance. In response to a petition completed pursuant to this chapter, the board may, in its sole discretion, issue an order waiving, in whole or in part, the requirements of a rule as applied to an identified person on the basis of the particular circumstances of that person if the board finds, based on clear and convincing evidence, all of the following:

66.3(1) The application of the rule would impose an undue hardship on the person for whom the waiver is requested;

66.3(2) The waiver from the requirements of the rule in the specific case would not prejudice the substantial legal rights of any person;

66.3(3) The provisions of the rule subject to the petition for a waiver are not specifically mandated by statute or another provision of law;

66.3(4) Substantially equal protection of public health, safety, and welfare will be afforded by a means other than that prescribed in the particular rule for which the waiver is requested; and

66.3(5) There is a reasonable relationship between the age of the conveyance and the variance requested.

[**ARC 8621B**, IAB 3/24/10, effective 4/28/10]

875—66.4(17A,89A) Filing of petition. A petition for a waiver must be submitted in writing to the board as follows:

66.4(1) *Contested cases.* If the petition relates to a pending contested case, the petition shall be filed in the contested case proceeding, using the caption of the contested case.

66.4(2) *Other.* If the petition does not relate to a pending contested case, the petition may be submitted with a caption containing the name of the person for whom the waiver is requested.

66.4(3) *Filing petition.* A petition is deemed filed when it is received in the board's office. A petition should be sent to the Elevator Safety Board, Department of Workforce Development, Division of Labor Services, 1000 East Grand Avenue, Des Moines, Iowa 50319. The petitioner shall submit the petition and all related materials for consideration at least three weeks prior to a scheduled board meeting for board review of the petition at the meeting.

[**ARC 8621B**, IAB 3/24/10, effective 4/28/10]

875—66.5(17A,89A) Content of petition. The required form for a petition for waiver or variance is available on the board's website at www.iowaelevators.gov. A petition for waiver shall include the following information where applicable and known to the petitioner:

66.5(1) The name, address, and telephone number of the entity or person for whom a waiver is being requested; the case number of or other reference to any related contested case; and the name, address, and telephone number of the petitioner's legal representative, if any.

66.5(2) A description of and citation to the specific rule from which a waiver is requested.

66.5(3) The specific waiver requested, including the precise scope and duration.

66.5(4) The relevant facts that the petitioner believes would justify a waiver under each of the five criteria described in rule 875—66.3(17A,89A). This statement shall include a signed statement from the

petitioner attesting to the accuracy of the facts provided in the petition and a statement of reasons that the petitioner believes will justify a waiver.

66.5(5) A history of any prior contacts between the board, other departments or agencies of the state of Iowa, or political subdivisions and the petitioner relating to the conveyance affected by the proposed waiver.

66.5(6) Information regarding the board's action in similar cases.

66.5(7) The name, address, and telephone number of any public agency or political subdivision which might be affected by the granting of a waiver.

66.5(8) The name, address, and telephone number of any entity or person who would be adversely affected by the granting of a petition.

66.5(9) The name, address, and telephone number of any person with knowledge of the relevant facts relating to the proposed waiver.

66.5(10) Signed releases of information authorizing persons with knowledge regarding the petition to furnish the board with information relevant to the petition for waiver.

66.5(11) The state identification number of the conveyance.

66.5(12) The age of the conveyance.

[**ARC 8621B**, IAB 3/24/10, effective 4/28/10; **ARC 3856C**, IAB 6/20/18, effective 8/1/18]

875—66.6(17A,89A) Additional information. Prior to issuing an order granting or denying a waiver, the board may request additional information from the petitioner relative to the petition and surrounding circumstances. If the petition was not filed in a contested case, the board may, on its own motion or at the petitioner's request, schedule a telephonic or in-person meeting between the petitioner and a representative or representatives of the board related to the waiver request.

[**ARC 8621B**, IAB 3/24/10, effective 4/28/10]

875—66.7(17A,89A) Notice. The board shall acknowledge a petition within ten days of its receipt in the board office. The board shall ensure that notice of the pending petition has been provided to all persons to whom notice is required by any provision of law within 30 days of the receipt of the petition. In addition, the board may give notice to other persons. To accomplish this notice provision, the board may require the petitioner to serve the notice on all persons to whom notice is required by any provision of law and to provide a written statement to the board attesting that notice has been provided.

875—66.8(17A,89A) Board review procedures.

66.8(1) Unless the board makes other arrangements, petitions for waiver will be reviewed and may be granted or denied at the next scheduled board meeting following receipt of the petition. However, if the petition is received less than three weeks prior to the scheduled board meeting, the petition will be reviewed at the subsequent meeting.

66.8(2) The petitioner shall be provided a reasonable opportunity to make a presentation to the board. The length of time allotted for presentation shall be reasonable in light of the complexity and number of issues involved.

875—66.9(17A,89A) Hearing procedures. The provisions of Iowa Code sections 17A.10 to 17A.18A regarding contested case hearings shall apply to any petition for a waiver filed within a contested case and shall otherwise apply to board proceedings for a waiver only when the board so provides by order or is required to do so by statute.

875—66.10(17A,89A) Ruling. An order granting or denying a waiver shall be in writing and shall contain a reference to the particular person or legal entity and rule or portion thereof to which the order pertains, a statement of the relevant facts and reasons upon which the action is based, and a description of the precise scope and duration of the waiver if one is issued.

66.10(1) *Board discretion.* The final decision on whether the circumstances justify the granting of a waiver shall be made at the sole discretion of the board, upon consideration of all relevant factors. Each

petition for a waiver shall be evaluated by the board based on the unique, individual circumstances set out in the petition.

66.10(2) *Burden of persuasion.* The burden of persuasion rests with the petitioner to demonstrate by clear and convincing evidence that the board should exercise its discretion to grant a waiver from a rule.

66.10(3) *Narrowly tailored exception.* A waiver, if granted, shall provide the narrowest exception possible to the provisions of a rule.

66.10(4) *Administrative deadlines.* When the rule from which a waiver is sought establishes administrative deadlines, the board shall balance the special individual circumstances of the petitioner with the overall goal of uniform treatment of all similarly situated persons.

66.10(5) *Conditions.* The board may place on a waiver any condition that the board finds desirable to protect the public health, safety, and welfare.

66.10(6) *Time period of waiver.* A waiver shall not be permanent unless the petitioner can show that a temporary waiver would be impracticable. If a temporary waiver is granted, there is no automatic right to renewal. At the sole discretion of the board, a waiver may be renewed if the board finds that grounds for a waiver continue to exist.

66.10(7) *Time for ruling.* The board shall grant or deny a petition for a waiver as soon as practical but, in any event, shall do so within 120 days of its receipt, unless the petitioner agrees to a later date. However, if a petition is filed in a contested case, the board shall grant or deny the petition no later than the time at which the final decision in that contested case is issued.

66.10(8) *When deemed denied.* Failure of the board to grant or deny a petition within the required time period shall be deemed a denial of that petition by the board. However, the board shall remain responsible for issuing an order denying a waiver.

66.10(9) *Service of order.* Within 14 days of the ruling, any order issued under this rule shall be transmitted or delivered to the petitioner or the person to whom the order pertains, and to any other person entitled to such notice by any provision of law.

66.10(10) *Posting of orders granting waivers.* The order or a copy of the order granting a waiver shall be conspicuously and permanently posted in the machine room corresponding to the conveyance. The order or a copy of the order granting a waiver that relates to a conveyance that does not have a machine room shall be posted in a protective sleeve attached to the inside of the controller cabinet door corresponding to the conveyance.

[**ARC 0168C**, IAB 6/13/12, effective 7/18/12]

875—66.11(17A,89A) Public availability. All orders granting or denying a waiver petition shall be indexed, filed, and available for public inspection as provided in Iowa Code section 17A.3. Petitions for a waiver and orders granting or denying a waiver petition are public records under Iowa Code chapter 22. If petitions or orders contain information the board is authorized or required to keep confidential, the board may instruct the board office to accordingly redact confidential information from petitions or orders prior to public inspection.

875—66.12(17A,89A) Summary reports. Summary information identifying the rules for which a waiver has been granted or denied, the number of times a waiver was granted or denied for each rule, a citation to the statutory provisions implemented by the rules, and a general summary of the reasons justifying the board's actions on waiver requests shall be included in semiannual reports prepared by the board. Copies of this report shall be provided to the administrative rules coordinator and the administrative rules review committee.

875—66.13(17A,89A) Cancellation of a waiver. A waiver issued by the board pursuant to this chapter may be withdrawn, canceled, or modified if, after appropriate notice and review, the board issues an order finding any of the following:

66.13(1) The petitioner or the person who was the subject of the waiver order withheld or misrepresented material facts relevant to the propriety or desirability of the waiver; or

66.13(2) The alternative means for ensuring that the public health, safety and welfare will be adequately protected after issuance of the waiver order have been demonstrated to be insufficient; or

66.13(3) The subject of the waiver order has failed to comply with all conditions contained in the order.

875—66.14(17A,89A) Violations. Violation of a condition in a waiver order shall be treated as a violation of the particular rule for which the waiver was granted. As a result, the recipient of a waiver under this rule who violates a condition of the waiver may be subject to the same remedies or penalties as a person who violates the rule at issue.

875—66.15(17A,89A) Defense. After the board issues an order granting a waiver, the order is a defense within its terms and the specific facts indicated therein only for the specific conveyance to which the order pertains in any proceeding in which the rule in question is sought to be invoked.

875—66.16(17A,89A) Judicial review. Judicial review of the board's decision to grant or deny a waiver petition may be taken in accordance with Iowa Code chapter 17A.

These rules are intended to implement Iowa Code chapters 17A, 22, and 89A.

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[Filed ARC 3856C (Notice ARC 3727C, IAB 4/11/18), IAB 6/20/18, effective 8/1/18]

CHAPTER 67
ELEVATOR SAFETY BOARD PETITIONS FOR RULE MAKING

875—67.1(17A,89A) Petitions for rule making. Any person or agency may file a petition for rule making with the board requesting the adoption, amendment or repeal of a rule. The required form for a petition for rule making is available on the board's website at www.iowaelevators.gov. The petition shall be filed at the location specified in rule 875—65.5(89A). A petition is deemed filed when it is received by the board office. The board office shall provide the petitioner with a file-stamped copy of the petition if the petitioner provides the board an extra copy for this purpose. The petition must be in writing and provide the following information where applicable and known to the petitioner:

67.1(1) A statement of the specific rule-making action sought by the petitioner including the text or a summary of the contents of the proposed rule or amendment to a rule and, if it is a petition to amend or repeal a rule, a citation to and the relevant language of the particular portion or portions of the rule proposed to be amended or repealed.

67.1(2) A citation to any law deemed relevant to the board's authority to take the action urged or to the desirability of that action.

67.1(3) A brief summary of petitioner's arguments in support of the action urged in the petition.

67.1(4) A brief summary of any data supporting the action urged in the petition.

67.1(5) The names and addresses of other persons, or a description of any class of persons, known by petitioner to be affected by or interested in the proposed action which is the subject of the petition.

67.1(6) The petition must be dated and signed by the petitioner or the petitioner's representative. The petition must also include the name, mailing address, and telephone number of the petitioner and petitioner's representative, and a statement indicating the person to whom communications concerning the petition should be directed.

67.1(7) The board may deny a petition because it does not provide the required information. The petitioner may file a new petition on the same subject that seeks to eliminate the grounds for the board's rejection.

[**ARC 8621B**, IAB 3/24/10, effective 4/28/10; **ARC 3856C**, IAB 6/20/18, effective 8/1/18]

875—67.2(17A,89A) Briefs. The petitioner may attach a brief to the petition in support of the action urged in the petition. The board may request a brief from the petitioner or from any other person concerning the substance of the petition.

875—67.3(17A,89A) Inquiries. Inquiries concerning the status of a petition for rule making may be made to Elevator Safety Board, Department of Workforce Development, Division of Labor Services, 1000 East Grand Avenue, Des Moines, Iowa 50319.

875—67.4(17A,89A) Board review procedures.

67.4(1) Unless the board makes other arrangements, petitions for rule making will be reviewed and may be granted or denied at the next scheduled board meeting following receipt of the petition. However, if the petition is received less than three weeks prior to the scheduled board meeting, the petition will be reviewed at the subsequent meeting. The board may request the petitioner to submit additional information or argument concerning the petition. The board may also solicit comments from any person on the substance of the petition. Also, comments on the substance of the petition may be submitted to the board by any person.

67.4(2) The petitioner shall be provided a reasonable opportunity to make a presentation to the board. The length of time allotted for presentation shall be reasonable in light of the complexity and number of issues involved.

67.4(3) Within 60 days after the filing of the petition, or within any longer period agreed to by the petitioner, the board shall deny the petition in writing and notify petitioner of its action and the specific grounds for the denial, or grant the petition and notify petitioner that the board will institute rule-making proceedings on the subject of the petition. Notice shall be sent by the board office to the petitioner by

regular mail. Petitioner shall be deemed notified of the denial or granting of the petition on the date the board office mails the required notification to the petitioner.

67.4(4) Denial of a petition because it does not contain the required information does not preclude the filing of a new petition on the same subject that seeks to eliminate the grounds for the board's rejection of the petition.

These rules are intended to implement Iowa Code chapters 17A and 89A.

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CHAPTER 68
DECLARATORY ORDERS BY THE ELEVATOR SAFETY BOARD

875—68.1(17A,89A) Petition for declaratory order. Any person may file at the board's offices a petition with the board for a declaratory order as to the applicability to specified circumstances of a statute, rule, or order within the primary jurisdiction of the board. A petition is deemed filed when it is received by that office. The board shall provide the petitioner with a file-stamped copy of the petition if the petitioner provides the board an extra copy for this purpose.

68.1(1) The required form for a petition for declaratory order is available on the board's website at www.iowaelevators.gov. The petition must be in writing and provide the following information where applicable and known to the petitioner:

a. A clear and concise statement of all relevant facts on which the order is requested.

b. A citation and the relevant language of the specific statutes, rules, or orders whose applicability is questioned, and any other relevant law.

c. Clear and concise questions the petitioner wants the board to answer.

d. The answers to the questions desired by the petitioner and a summary of the reasons urged by the petitioner in support of those answers.

e. The reasons for requesting the declaratory order and disclosure of the petitioner's interest in the outcome.

f. A statement indicating whether the petitioner is currently a party to another proceeding involving the questions at issue and whether, to the petitioner's knowledge, those questions have been directed by, are pending determination by, or are under investigation by any governmental entity.

g. The names and addresses of other persons, or a description of any class of persons, known by petitioner to be affected by, or interested in, the questions in the petition.

68.1(2) The petition must be dated and signed by the petitioner or the petitioner's representative. It must also include the name, mailing address, and telephone number of the petitioner and petitioner's representative, and a statement indicating the person to whom communications concerning the petition should be directed.

[**ARC 8621B**, IAB 3/24/10, effective 4/28/10; **ARC 0168C**, IAB 6/13/12, effective 7/18/12; **ARC 3856C**, IAB 6/20/18, effective 8/1/18]

875—68.2(17A,89A) Notice of petition. Within 15 days after receipt of a petition for a declaratory order, the board shall give notice of the petition to all persons not served by the petitioner pursuant to rule 875—68.6(17A,89A) to whom notice is required by any provision of law. The board may also give notice to any other persons.

875—68.3(17A,89A) Intervention.

68.3(1) A person who qualifies under any applicable provision of law as an intervenor and who files a petition for intervention within 20 days of the filing of a petition for declaratory order shall be allowed to intervene in a proceeding for a declaratory order.

68.3(2) At the board's discretion, a person who files a petition for intervention more than 20 days after the filing of a petition for declaratory order but prior to the issuance of an order may be allowed to intervene in a proceeding for a declaratory order.

68.3(3) A petition for intervention shall be filed at the board office. Such a petition is deemed filed when it is received by that office. The board will provide the petitioner with a file-stamped copy of the petition for intervention if the petitioner provides an extra copy for this purpose.

a. A petition for intervention must be in writing and provide the following information where applicable and known to the requester:

(1) Facts supporting the intervenor's standing and qualifications for intervention.

(2) The answers urged by the intervenor to the question or questions presented and a summary of the reasons urged in support of those answers.

(3) Reasons for requesting intervention and disclosure of the intervenor's interest in the outcome.

(4) A statement indicating whether the intervenor is currently a party to any proceeding involving the questions at issue and whether, to the intervenor's knowledge, those questions have been decided by, are pending determination by, or are under investigation by any governmental entity.

(5) The names and addresses of any additional persons, or a description of any additional class of persons, known by the intervenor to be affected by, or interested in, the questions presented.

(6) Whether the intervenor consents to be bound by the determination of the matters presented in the declaratory order proceeding.

b. The petition must be dated and signed by the intervenor or the intervenor's representative. It must also include the name, mailing address, and telephone number of the intervenor and intervenor's representative, and a statement indicating the person to whom communications should be directed.
[**ARC 8621B**, IAB 3/24/10, effective 4/28/10]

875—68.4(17A,89A) Briefs. The petitioner or intervenor may file a brief in support of the position urged. The board may request a brief from the petitioner, any intervenor, or any other person concerning the questions raised in the petition.

875—68.5(17A,89A) Inquiries. Inquiries concerning the status of a declaratory order may be made at the board office.

875—68.6(17A,89A) Service and filing of petitions and other papers.

68.6(1) *When service required.* Except where otherwise provided by law, every petition for declaratory order, petition for intervention, brief, or other paper filed in a proceeding for a declaratory order shall be served upon each of the parties of record to the proceeding, and on all other persons identified in the petition for declaratory order or petition for intervention as affected by or interested in the questions presented, simultaneously with its filing. The party filing a document is responsible for service on all parties and other affected or interested persons.

68.6(2) *Filing—when required.* All petitions for declaratory orders, petitions for intervention, briefs, or other papers in a proceeding for a declaratory order shall be filed with the board at the board office. All petitions, briefs, or other papers that are required to be served upon a party shall be filed simultaneously with the board.

68.6(3) *Method of service, time of filing, and proof of mailing.* Method of service, time of filing, and proof of mailing shall be as provided by rules 875—69.10(17A,89A) and 875—69.11(17A,89A).

875—68.7(17A,89A) Board review procedures.

68.7(1) Within 30 days after receipt of a petition for a declaratory order, the board shall issue a document that does one of the following:

a. Declares the applicability of the statute, rule or order to the specified circumstances,

b. Sets the matter for specific proceedings,

c. Agrees to issue a declaratory order by a specified time, or

d. Declines to issue a declaratory order and sets forth the reasons for its actions as provided in subrule 68.9(1).

68.7(2) The board may request the petitioner to submit additional information or argument concerning the petition. The board may also solicit comments from any person on the substance of the petition. Also, comments on the substance of the petition may be submitted to the board by any person.

68.7(3) The petitioner and all intervenors shall be provided a reasonable opportunity to make a presentation to the board. The length of time allotted for presentation shall be reasonable in light of the complexity and number of issues involved.
[**ARC 8621B**, IAB 3/24/10, effective 4/28/10]

875—68.8(17A,89A) Action on petition. Rescinded IAB 3/24/10, effective 4/28/10.

875—68.9(17A,89A) Refusal to issue order.

68.9(1) The board shall not issue a declaratory order where prohibited by Iowa Code section 17A.9(1) and may refuse to issue a declaratory order on some or all questions raised for the following reasons:

a. The petition does not provide the required information.

b. Rescinded IAB 3/24/10, effective 4/28/10.

c. The board does not have jurisdiction over the questions presented in the petition.

d. The questions presented by the petition are also presented in a current rule making, contested case, or other board or judicial proceeding that may definitively resolve them.

e. The questions presented by the petition would more properly be resolved in a different type of proceeding or by another body with jurisdiction over the matter.

f. The facts or questions presented in the petition are unclear, overbroad, insufficient, or otherwise inappropriate as a basis upon which to issue an order.

g. There is no need to issue an order because the questions raised in the petition have been settled due to a change in circumstances.

h. The petition is not based upon facts calculated to aid in the planning of future conduct but is, instead, based solely upon prior conduct in an effort to establish the effect of that conduct or to challenge a board decision already made.

i. The petition requests a declaratory order that would necessarily determine the legal rights, duties, or responsibilities of other persons who have not joined in the petition or filed a similar petition and whose position on the questions presented may fairly be presumed to be adverse to that of petitioner.

j. The petitioner requests the board to determine whether a statute is unconstitutional on its face.

68.9(2) A refusal to issue a declaratory order must indicate the specific grounds for the refusal and constitutes final board action on the petition.

68.9(3) Refusal to issue a declaratory order pursuant to this provision does not preclude the filing of a new petition that seeks to eliminate the grounds for refusal to issue an order.

[**ARC 8621B**, IAB 3/24/10, effective 4/28/10]

875—68.10(17A,89A) Contents of declaratory order—effective date. In addition to the ruling itself, a declaratory order must contain the date of its issuance, the name of petitioner and all intervenors, the specific statutes, rules, policies, decisions, or orders involved, the particular facts upon which it is based, and the reasons for its conclusion. A declaratory order is effective on the date of issuance.

875—68.11(17A,89A) Copies of orders. A copy of all orders issued in response to a petition for a declaratory order shall be mailed promptly to the original petitioner and all intervenors.

875—68.12(17A,89A) Effect of a declaratory order. A declaratory order has the same status and binding effect as a final order in a contested case proceeding. It is binding on the board, the petitioner and any intervenors and is applicable only in circumstances where the relevant facts and the law involved are indistinguishable from those on which the order was based. As to all other persons, a declaratory order serves only as precedent and is not binding on the board. The issuance of a declaratory order constitutes final board action on the petition.

These rules are intended to implement Iowa Code chapters 17A and 89A.

[Filed 6/16/06, Notice 5/10/06—published 7/5/06, effective 8/9/06]
[Filed ARC 8621B (Notice ARC 8322B, IAB 12/2/09), IAB 3/24/10, effective 4/28/10]
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[Filed ARC 3856C (Notice ARC 3727C, IAB 4/11/18), IAB 6/20/18, effective 8/1/18]

CHAPTER 69
CONTESTED CASES BEFORE THE ELEVATOR SAFETY BOARD

875—69.1(17A,89A) Reconsideration of inspection report. The owner or operator of a piece of equipment subject to a written inspection report may petition the commissioner for reconsideration of the report within 30 days of the issuance of the report. Failure to seek timely reconsideration of the inspection report from the commissioner shall be deemed a waiver of all appeal rights under Iowa Code section 89A.13(5). The burden of demonstrating compliance with all applicable statutory provisions, administrative rules, and codes adopted by reference rests upon the petitioning owner or operator.

69.1(1) A petition for reconsideration shall be in writing and must be signed by the requesting party or a representative of that party. The required form for a petition for reconsideration is available on the board's website at www.iowaelevators.gov. A petition for reconsideration shall specify:

a. The party seeking reconsideration, including mailing address and telephone number;
b. The location of the equipment subject to the challenged inspection report;
c. The inspection date;
d. The inspector who issued the challenged inspection report;
e. The specific findings or conclusions to which exception is taken;
f. The relief sought.

69.1(2) A copy of the challenged inspection report shall be attached to the petition for reconsideration. The petitioning party shall also include all relevant documents that the petitioning party desires the commissioner to consider when evaluating the petition.

69.1(3) The commissioner or a designee of the commissioner is authorized to seek additional information relating to a petition for reconsideration from the petitioning party or any other entity possessing information the commissioner deems relevant to the petition. This subrule, however, does not impose any responsibility or duty on the commissioner to discover documents or other information that was not submitted with the petition for reconsideration.

69.1(4) Any petition for reconsideration that is not received by the office of the commissioner within 30 days of the issuance of the challenged inspection report shall be deemed untimely and will not be considered by the commissioner.

69.1(5) The commissioner shall not consider any request for waiver or variance of an administrative rule made as part of a petition for reconsideration. Requests for waivers or variances of administrative rules may only be made to the board pursuant to the provisions of 875—Chapter 66.

69.1(6) The commissioner shall issue a written ruling on the petition for reconsideration. In ruling on a petition for reconsideration, the commissioner may:

a. Affirm the inspection report as issued;
b. Issue an amended inspection report;
c. Rescind the inspection report;
d. Deny the petition as untimely.

69.1(7) Any petition for reconsideration that is not ruled upon by the commissioner within 20 days of receipt by the office of the commissioner shall be deemed denied by the commissioner and the challenged inspection report shall be considered affirmed as issued.

[**ARC 8621B**, IAB 3/24/10, effective 4/28/10; **ARC 3856C**, IAB 6/20/18, effective 8/1/18]

875—69.2(17A,89A) Appeal to the board.

69.2(1) A decision by the commissioner to deny, suspend, or revoke an operating permit; a deemed denial of a petition for reconsideration; and the commissioner's ruling on a petition for reconsideration are subject to appeal to the board.

69.2(2) An appeal to the board shall be a contested case proceeding subject to the provisions of Iowa Code chapter 17A.

69.2(3) The commissioner shall have an automatic right of intervention in any appeal and shall defend the ruling in a contested case proceeding.

69.2(4) Only those issues raised by the petitioner in the petition for reconsideration will be preserved for appeal to the board in an appeal from the deemed denial of a petition for reconsideration and an appeal from the commissioner's ruling on a petition for reconsideration.

69.2(5) At a minimum, an appeal shall include a short and concise statement of the basis for the appeal. The required form for an appeal to the board is available on the board's website at www.iowaelevators.gov.

69.2(6) The deadlines for filing an appeal are set forth below:

a. Reconsideration of an inspection report. An appeal must be filed in writing with the board within 30 calendar days of the earlier of either the issuance of the commissioner's written ruling on a petition for reconsideration or the deemed denial of a petition for reconsideration.

b. Notification of intent to deny, suspend, or revoke an operating permit. An appeal must be filed in writing with the board within 30 calendar days of the appellant's receipt of the notification of intent to deny, suspend, or revoke an operating permit.

[**ARC 8621B**, IAB 3/24/10, effective 4/28/10; **ARC 0168C**, IAB 6/13/12, effective 7/18/12; **ARC 3856C**, IAB 6/20/18, effective 8/1/18]

875—69.3(17A,89A) Informal review. If the appellant requests and the commissioner does not object, the board may conduct an informal review of the facts and circumstances subject to the provisions of this rule.

69.3(1) In order to preserve the ability of board members to participate in decision making, a party who elects an informal review under this rule waives the party's right to seek disqualification of a board member as a presiding officer in a later contested case proceeding based on the board member's participation in the informal review. A party who elects informal review retains the right to seek disqualification of board members on any other ground pursuant to subrule 69.14(4).

69.3(2) The board may propose a preliminary order at the time of informal review. If a party does not consent to the preliminary order, a party must submit a request to proceed with formal contested case proceedings, including hearing, within ten days of the informal review.

69.3(3) Rules 875—69.4(17A,89A) through 875—69.31(17A,89A) do not apply during informal review.

[**ARC 8621B**, IAB 3/24/10, effective 4/28/10; **ARC 0168C**, IAB 6/13/12, effective 7/18/12]

875—69.4(17A,89A) Delivery of notice. Delivery of the notice of hearing by the board constitutes the commencement of a contested case proceeding. Delivery may be executed by regular mail. The notice shall be delivered to the appellant, the appellant's attorney, if known, and the commissioner.

875—69.5(17A,89A) Contents of notice. The notice of hearing shall contain a statement of the time, place, and nature of the hearing. The notice shall contain a short and plain statement of the matters asserted. If the board is unable to state the matters in detail at the time the notice is served, the initial notice may be limited to a statement of the issues involved. Thereafter, upon application, a more definite and detailed statement shall be furnished. The notice shall contain a statement that it is the appellant's burden on appeal to prove compliance with all applicable statutory provisions, administrative rules, and ASME code sections. The notice shall also contain a reference to the applicable statute and rules.

875—69.6(17A,89A) Scope of issues. Rescinded IAB 6/13/12, effective 7/18/12.

875—69.7(17A,89A) File transmitted to the board. Within 30 days of the issuance of a notice of hearing, the commissioner shall forward to each board member and all parties of record to the appeal copies of the applicable documents set forth below:

1. Inspection report,
2. Petition for reconsideration with the appellant's attachments,
3. Documents obtained by the commissioner in ruling on the petition for reconsideration,
4. Commissioner's ruling on the petition for reconsideration,
5. Commissioner's decision denying, suspending, or revoking an operating permit, and

6. Appeal to the board.

[**ARC 8621B**, IAB 3/24/10, effective 4/28/10; **ARC 0168C**, IAB 6/13/12, effective 7/18/12]

875—69.8(17A,89A) Legal representation. Any private party to a contested case shall be entitled to legal representation at the discretion and expense of that party.

875—69.9(17A,89A) Presiding officer.

69.9(1) The presiding officer in all contested cases shall be the board, a panel of board members, or an administrative law judge assigned by the department of inspections and appeals. When board members act as presiding officer, they shall conduct the hearing and issue either a final decision or, if a quorum of the board is not present, a proposed decision. As provided in subrule 69.9(4), the board may be assisted by an administrative law judge when the board acts as presiding officer.

69.9(2) Any party to a contested case that wishes to request that the presiding officer assigned to render a proposed decision be an administrative law judge employed by the department of inspections and appeals must file a written request within 20 days after service of a notice of hearing which identifies the presiding officer as the board. The board may deny the request only upon a finding that one or more of the following apply:

a. Neither the board nor any officer of the board under whose authority the contested case is to take place is a named party to the proceeding or a real party in interest to that proceeding.

b. There is a compelling need to expedite issuance of a final decision in order to protect the public health, safety, or welfare.

c. The case involves significant policy issues of first impression that are inextricably intertwined with the factual issues presented.

d. The demeanor of the witnesses is likely to be dispositive in resolving the disputed factual issues.

e. Funds are unavailable to pay the costs of an administrative law judge and an intra-agency appeal.

f. The request was not timely filed.

g. The request is not consistent with a specified statute.

69.9(3) The board shall issue a written ruling specifying the grounds for its decision within 20 days after a request for an administrative law judge is filed. If the ruling is granted, the administrative law judge assigned to act as presiding officer and to issue a proposed decision in a contested case shall have a J.D. degree unless this requirement is waived by the board.

69.9(4) The board or a panel of board members when acting as presiding officer may request that an administrative law judge perform certain functions as an aid to the board or board panel, such as ruling on prehearing motions, conducting the prehearing conference, ruling on evidentiary objections at hearing, assisting in deliberations, or drafting the written decision for review by the board or board panel.

69.9(5) All rulings by an administrative law judge who acts either as presiding officer or assistant to the board are subject to appeal to the board pursuant to rules 875—69.26(17A,89A) and 875—69.27(17A,89A). A party must timely seek intra-agency appeal of prehearing rulings or proposed decisions in order to exhaust adequate administrative remedies. While a party may seek immediate board or board panel review of rulings made by an administrative law judge when sitting with and acting as an aid to the board or board panel during a hearing, such immediate review is not required to preserve error for judicial review.

69.9(6) Unless otherwise provided by law, when reviewing a proposed decision of a panel of the board or an administrative law judge, board members shall have the powers of and shall comply with the provisions of this chapter that apply to presiding officers.

[**ARC 0168C**, IAB 6/13/12, effective 7/18/12]

875—69.10(17A,89A) Service and filing.

69.10(1) *Service—when required.* Except where otherwise provided by law, every document filed in a contested case proceeding shall be served upon each of the parties of record. Except for the original notice of hearing and an application for rehearing as provided in Iowa Code section 17A.16, subsection 2, the party filing a document is responsible for service on all parties.

69.10(2) *Service—how made.* Service upon a party represented by an attorney shall be made upon the attorney unless otherwise ordered. Service is made by personal delivery or by mailing a copy to the person's last-known address. Service by mail is complete upon mailing, except where otherwise specifically provided by statute, rule, or order.

69.10(3) *Filing—when required.* All documents that are required to be served upon a party shall be filed simultaneously with the board.

69.10(4) *Filing—when made.* Except where otherwise provided by law, a document is deemed filed at the time it is delivered to the board at the location set forth in rule 875—65.5(89A), delivered to an established courier service for immediate delivery to that office, or mailed by first-class mail or state interoffice mail to that office, so long as there is proof of mailing.

69.10(5) *Proof of mailing.* Proof of mailing includes either:

a. A legible United States Postal Service postmark on the envelope;

b. A certified mail return receipt;

c. A notarized affidavit; or

d. A certification in substantially the following form:

I certify under penalty of perjury and pursuant to the laws of Iowa that, on (date of mailing), I mailed copies of (describe document) addressed to the Elevator Safety Board, Department of Workforce Development, Division of Labor Services, 1000 East Grand Avenue, Des Moines, Iowa 50319, and to the names and addresses of the parties listed below by depositing the same in a United States post office mailbox with correct postage properly affixed.

(Date) (Signature)

[**ARC 8621B**, IAB 3/24/10, effective 4/28/10; **ARC 0168C**, IAB 6/13/12, effective 7/18/12]

875—69.11(17A,89A) Time requirements.

69.11(1) Time shall be computed as provided in Iowa Code subsection 4.1(34).

69.11(2) For good cause, the presiding officer may extend or shorten the time to take any action, except as precluded by statute. Except for good cause stated in the record, before extending or shortening the time to take any action, the presiding officer shall afford all parties an opportunity to be heard or to file written arguments.

875—69.12(17A,89A) Waiver of procedures. Unless otherwise precluded by law, the parties in a contested case proceeding may waive any provision of this chapter. However, the board in its discretion may refuse to give effect to such a waiver when the board deems the waiver to be inconsistent with the public interest.

875—69.13(17A,89A) Telephone and electronic proceedings. The presiding officer may, on the officer's own motion or as requested by a party, order hearings or argument to be held by telephone conference or other electronic means in which all parties have an opportunity to participate. The presiding officer will determine the location of the parties and witnesses for telephone or other electronic hearings. The convenience of the witnesses or parties, as well as the nature of the case, will be considered when location is chosen. Parties shall disclose at or before the prehearing conference if any witness will be testifying by telephone. Objections, if any, shall be filed with the board and served on all parties at least three business days in advance of hearing.

875—69.14(17A,89A) Disqualification.

69.14(1) A presiding officer or other person shall withdraw from participation in the making of any proposed or final decision in a contested case if that person:

a. Has a personal bias or prejudice concerning a party or a representative of a party;

b. Has personally investigated, prosecuted or advocated in connection with that case, the specific controversy underlying that case, another pending factually related contested case, or a pending factually related controversy that may culminate in a contested case involving the same parties;

c. Is subject to the authority, direction or discretion of any person who has personally investigated, prosecuted or advocated, in connection with that contested case, the specific controversy underlying that contested case, or a pending factually related contested case or controversy involving the same parties;

d. Has acted as counsel to any person who is a private party to that proceeding within the past two years;

e. Has a personal financial interest in the outcome of the case or any other significant personal interest that could be substantially affected by the outcome of the case;

f. Has a spouse or relative within the third degree of relationship that (1) is a party to the case, or an officer, director or trustee of a party; (2) is a lawyer in the case; (3) is known to have an interest that could be substantially affected by the outcome of the case; or (4) is likely to be a material witness in the case; or

g. Has any other legally sufficient cause to withdraw from participation in the decision making in that case.

69.14(2) The term "personally investigated" means taking affirmative steps to interview witnesses directly or to obtain documents or other information directly. The term "personally investigated" does not include general direction and supervision of assigned investigators, unsolicited receipt of information which is relayed to assigned investigators, review of another person's investigative work product in the course of determining whether there is probable cause to initiate a proceeding, or exposure to factual information while performing other board functions, including fact gathering for purposes other than investigation of the matter which culminates in a contested case. Factual information relevant to the merits of a contested case received by a person who later serves as presiding officer in that case shall be disclosed if required by Iowa Code section 17A.17(3) and subrule 69.25(7).

69.14(3) In a situation where a presiding officer or other person knows of information which might reasonably be deemed to be a basis for disqualification and decides voluntary withdrawal is unnecessary, that person shall submit the relevant information for the record by affidavit and shall provide for the record a statement of the reasons for the determination that withdrawal is unnecessary.

69.14(4) If a party asserts disqualification on any appropriate ground, including those listed in subrule 69.14(1), the party shall file a motion supported by an affidavit pursuant to Iowa Code section 17A.17(7). The motion must be filed as soon as practicable after the reason alleged in the motion becomes known to the party.

69.14(5) If, during the course of the hearing, a party first becomes aware of evidence of bias or other grounds for disqualification, the party may move for disqualification but must establish the grounds by the introduction of evidence into the record.

69.14(6) If the presiding officer determines that disqualification is appropriate, the presiding officer or other person shall withdraw. If the presiding officer determines that withdrawal is not required, the presiding officer shall enter an order to that effect. A party asserting disqualification may seek an interlocutory appeal under rule 875—69.26(17A,89A) and seek a stay under rule 875—69.30(17A,89A).

875—69.15(17A,89A) Consolidation and severance.

69.15(1) *Consolidation.* The presiding officer may consolidate any or all matters at issue in two or more contested case proceedings where:

a. The matters at issue involve common parties or common questions of fact or law;

b. Consolidation would expedite and simplify consideration of the issues involved; and

c. Consolidation would not adversely affect the rights of any party to those proceedings.

69.15(2) *Severance.* The presiding officer may, for good cause shown, order any contested case proceedings or portions thereof severed.

[**ARC 0168C**, IAB 6/13/12, effective 7/18/12]

875—69.16(17A,89A) Discovery.

69.16(1) Pursuant to Iowa Code chapter 17A, discovery procedures applicable in civil actions are applicable in contested cases. Unless lengthened or shortened by these rules or by order of the presiding

officer, time periods for compliance with discovery shall be as provided in the Iowa Rules of Civil Procedure.

69.16(2) Any motion relating to discovery shall allege that the moving party has previously made a good-faith attempt to resolve with the opposing party the discovery issues involved. Motions in regard to discovery shall be ruled upon by the presiding officer. Opposing parties shall be afforded the opportunity to respond within ten days of the filing of the motion unless the time is shortened by order of the presiding officer. The presiding officer may rule on the basis of the written motion and any response, or may order argument on the motion.

875—69.17(17A,89A) Subpoenas in a contested case. Pursuant to Iowa Code section 17A.13, subsection 1, the board or the presiding officer acting on behalf of the board has the authority to issue subpoenas to compel the attendance of witnesses at depositions or hearings and to compel the production of professional records, books, papers, correspondence and other records which are deemed necessary as evidence in connection with a contested case. A subpoena issued in a contested case under the board's authority may seek evidence whether or not privileged or confidential under law.

69.17(1) Upon the written request of a party, the presiding officer shall issue a subpoena to compel the attendance of witnesses or to obtain evidence which is deemed necessary in connection with a contested case. A command to produce evidence may be joined with a command to appear at deposition or hearing or may be issued separately.

69.17(2) A request for a subpoena shall include the following information, as applicable:

a. The name, address and telephone number of the person requesting the subpoena;

b. The name and address of the person to whom the subpoena shall be directed;

c. The date, time, and location at which the person shall be commanded to attend and give testimony;

d. Whether the testimony is requested in connection with a deposition or hearing;

e. A description of the books, papers, records or other evidence requested;

f. The date, time and location for production, or inspection and copying.

69.17(3) Each subpoena shall contain, as applicable:

a. The caption of the case;

b. The name, address and telephone number of the person who requested the subpoena;

c. The name and address of the person to whom the subpoena is directed;

d. The date, time, and location at which the person is commanded to appear;

e. Whether the testimony is commanded in connection with a deposition or hearing;

f. A description of the books, papers, records or other evidence the person is commanded to produce;

g. The date, time and location for production, or inspection and copying;

h. The time within which a motion to quash or modify the subpoena must be filed;

i. The signature, address and telephone number of the presiding officer;

j. The date of issuance;

k. A return of service attached to the subpoena.

69.17(4) The presiding officer shall mail or otherwise provide copies of all subpoenas to the parties to the contested case. The person who requested the subpoena is responsible for serving the subpoena upon the subject of the subpoena.

69.17(5) Any person who is aggrieved or adversely affected by compliance with the subpoena or any party to the contested case who desires to challenge the subpoena must, within 14 days after service of the subpoena, or before the time specified for compliance if such time is less than 14 days, file with the board a motion to quash or modify the subpoena. The motion shall describe the legal reasons why the subpoena should be quashed or modified, and may be accompanied by legal briefs or factual affidavits.

69.17(6) Upon receipt of a timely motion to quash or modify a subpoena, the board chairperson shall request an administrative law judge to hold a hearing and issue a decision. Oral argument may be scheduled at the discretion of the board or the administrative law judge. The administrative law judge may quash or modify the subpoena or deny the motion.

69.17(7) A person aggrieved by a ruling of an administrative law judge who desires to challenge that ruling must appeal the ruling to the board by serving on the board, either in person or by certified mail, a notice of appeal within ten days after service of the decision of the administrative law judge. If the decision of the administrative law judge to quash or modify the subpoena or to deny the motion to quash or modify the subpoena is appealed to the board, the board may uphold or overturn the decision of the administrative law judge.

69.17(8) If the person contesting the subpoena is not the party whose appeal is the subject of the contested case, the board's decision is final for purposes of judicial review. If the person contesting the subpoena is the party whose appeal is the subject of the contested case, the board's decision is not final for purposes of judicial review until there is a final decision in the contested case.

[**ARC 8621B**, IAB 3/24/10, effective 4/28/10; **ARC 0168C**, IAB 6/13/12, effective 7/18/12]

875—69.18(17A,89A) Motions.

69.18(1) No technical form for motions is required. However, prehearing motions must be in writing, state the grounds for relief, and state the relief sought.

69.18(2) Any party may file a written response to a motion within ten days after the motion is served, unless the time period is extended or shortened by rules of the board or the presiding officer. The presiding officer may consider a failure to respond within the required time period in ruling on a motion.

69.18(3) The presiding officer may schedule oral argument on any motion.

69.18(4) Motions pertaining to the hearing, except motions for summary judgment, must be filed and served at least ten days prior to the date of hearing unless there is good cause for permitting later action or the time for such action is lengthened or shortened by rule of the board or an order of the presiding officer.

69.18(5) Motions for summary judgment shall comply with the requirements of Iowa Rule of Civil Procedure 1.981 and shall be subject to disposition according to the requirements of that rule to the extent such requirements are not inconsistent with the provisions of this rule or any other provision of law governing the procedure in contested cases. Motions for summary judgment must be filed and served at least 45 days prior to the scheduled hearing date, or other time period determined by the presiding officer. Any party resisting the motion shall file and serve a resistance within 15 days, unless otherwise ordered by the presiding officer, from the date a copy of the motion was served. The time fixed for hearing or nonoral submission shall be not less than 20 days after the filing of the motion, unless a shorter time is ordered by the presiding officer. A summary judgment order rendered on all issues in a contested case is subject to rehearing pursuant to rule 875—69.29(89A) and appeal pursuant to subrule 69.27(3).

875—69.19(17A,89A) Settlements. A contested case may be resolved by informal settlement, and settlements are encouraged. Settlement negotiations may be initiated at any stage of a contested case by any party. All settlements are subject to approval by a majority of the board. No settlement shall be presented to the board for approval except in final, written form executed by the parties. If the board fails to approve the settlement, the settlement shall be of no force or effect to either party.

[**ARC 0168C**, IAB 6/13/12, effective 7/18/12]

875—69.20(17A,89A) Prehearing conference.

69.20(1) Any party may request a prehearing conference. A written request for prehearing conference or an order for prehearing conference on the presiding officer's own motion shall be filed not less than seven days prior to the hearing date. A prehearing conference shall be scheduled not less than three business days prior to the hearing date. Written notice of the prehearing conference shall be given by the presiding officer to all parties. For good cause, the presiding officer may permit variances from this rule.

69.20(2) Each party shall bring to the prehearing conference:

a. A final list of the witnesses who the party anticipates will testify at hearing. Witnesses not listed may be excluded from testifying unless there was good cause for the failure to include their names.

b. A final list of exhibits which the party anticipates will be introduced at hearing. Exhibits other than rebuttal exhibits that are not listed may be excluded from admission into evidence unless there was good cause for the failure to include them.

c. Witness or exhibit lists may be amended subsequent to the prehearing conference within the time limits established by the presiding officer at the prehearing conference. Any such amendments must be served on all parties.

69.20(3) In addition to the requirements of subrule 69.20(2), the parties at a prehearing conference may:

a. Enter into stipulations of law or fact;

b. Enter into stipulations on the admissibility of exhibits;

c. Identify matters that the parties intend to request be officially noticed;

d. Enter into stipulations for waiver of any provision of law; and

e. Consider any additional matters that will expedite the hearing.

69.20(4) Prehearing conferences shall be conducted by telephone unless otherwise ordered. Parties shall exchange and receive witness and exhibit lists in advance of a telephone prehearing conference.

875—69.21(17A,89A) Continuances. Unless otherwise provided, applications for continuances shall be made to the presiding officer.

69.21(1) A written application for a continuance shall:

a. Be made at the earliest possible time and no less than seven days before the hearing except in case of unanticipated emergencies;

b. State the specific reasons for the request; and

c. Be signed by the requesting party or the party's representative.

An oral application for a continuance may be made if the presiding officer waives the requirement for a written motion. However, a party making such an oral application for a continuance must confirm that request by written application within five days after the oral request unless that requirement is waived by the presiding officer. No application for continuance shall be made or granted without notice to all parties except in an emergency where notice is not feasible. The presiding officer may waive notice of such requests for a particular case or an entire class of cases.

69.21(2) In determining whether to grant a continuance, the presiding officer may consider:

a. Prior continuances;

b. The interests of all parties;

c. The likelihood of informal settlement;

d. The existence of an emergency;

e. Any objection;

f. Any applicable time requirements;

g. The existence of a conflict in the schedules of counsel, parties, or witnesses;

h. The timeliness of the request; and

i. Other relevant factors.

The presiding officer may require documentation of any grounds for continuance.

875—69.22(17A,89A) Withdrawals. A party requesting a contested case proceeding may withdraw that request prior to the hearing. Unless otherwise provided, a withdrawal shall be with prejudice.

875—69.23(17A,89A) Hearing procedures.

69.23(1) The presiding officer shall have the authority to administer oaths, to admit or exclude testimony or other evidence, and to rule on all motions and objections.

69.23(2) All objections shall be timely made and stated on the record.

69.23(3) Parties have the right to participate or to be represented in all hearings or prehearing conferences related to their case. Any party may be represented by an attorney at the party's own expense.

69.23(4) Subject to terms and conditions prescribed by the presiding officer, parties have the right to introduce evidence on issues of material fact, cross-examine witnesses present at the hearing as necessary for a full and true disclosure of the facts, present evidence in rebuttal, and submit briefs and engage in oral argument.

69.23(5) The presiding officer shall maintain the decorum of the hearing and may refuse to admit or may expel anyone whose conduct is disorderly.

69.23(6) Witnesses may be sequestered during the hearing.

69.23(7) The presiding officer shall conduct the hearing in the following manner:

a. The presiding officer shall give an opening statement briefly describing the nature of the proceedings.

b. The parties shall be given an opportunity to present opening statements.

c. The parties shall present their cases in the sequence determined by the presiding officer.

d. Each witness shall be sworn or affirmed by the presiding officer or the court reporter, and be subject to examination and cross-examination. The presiding officer may limit questioning in a manner consistent with law.

e. When all parties and witnesses have been heard, the parties may be given the opportunity to present final arguments.

f. The presiding officer may enter a default judgment against a party who fails to appear at the hearing.

69.23(8) The presiding officer has the right to question a witness. Examination of witnesses by the presiding officer is subject to properly raised objections.

69.23(9) The hearing shall be open to the public, except as otherwise provided by law.

69.23(10) Oral proceedings shall be electronically recorded. Upon request, the board shall provide a copy of the whole or any portion of the audio recording at a reasonable cost. A certified shorthand reporter may be engaged to record the proceeding at the request of a party and at the expense of the party making the request. A transcription of the record of the hearing shall be made at the request of either party at the expense of the party making the request. The parties may agree to divide the cost of the transcription. A record of the proceedings, which may be either the original recording, a copy, or a transcript, shall be retained by the board for five years after the resolution of the case.

69.23(11) Default.

a. If a party fails to appear or participate in a contested case proceeding after proper service of notice, the presiding officer may, if no continuance is granted, enter a default decision or proceed with the hearing and render a decision in the absence of the party.

b. Where appropriate and not contrary to law, any party may move for default against a party who has requested the contested case proceeding and has failed to file a required pleading or has failed to appear after proper service.

c. Default decisions or decisions rendered on the merits after a party has failed to appear or participate in a contested case proceeding become final board action unless, within 15 days after the date of notification or mailing of the decision, a motion to vacate is filed and served on all parties or an appeal of a decision on the merits is timely initiated within the time provided by subrule 69.27(3). A motion to vacate must state all facts relied upon by the moving party that establish good cause existed for that party's failure to appear or participate at the contested case proceeding. Each fact must be substantiated by at least one attached, sworn affidavit of a person with personal knowledge.

d. The time for further appeal of a decision for which a timely motion to vacate has been filed is stayed pending a decision on the motion to vacate.

e. Properly substantiated and timely filed motions to vacate shall be granted only for good cause shown. The burden of proof as to good cause is on the moving party. Adverse parties shall have ten days to respond to a motion to vacate. Adverse parties shall be allowed to conduct discovery as to the issue of good cause and to present evidence on the issue prior to a decision on the motion, if a request to do so is included in that party's response.

f. "Good cause" for purposes of this rule shall have the same meaning as "good cause" for setting aside a default judgment under Iowa Rule of Civil Procedure 1.977.

g. A decision denying a motion to vacate is subject to further appeal within the time limit allowed for further appeal of a decision on the merits in the contested case proceeding.

h. If a motion to vacate is granted and no timely interlocutory appeal has been taken, the presiding officer shall issue another notice of hearing and the contested case shall proceed accordingly.

i. A default decision may award any relief consistent with the request for relief made in the petition and embraced in its issues but, unless the defaulting party has appeared, it cannot exceed the relief demanded.

[**ARC 8621B**, IAB 3/24/10, effective 4/28/10]

875—69.24(17A,89A) Evidence.

69.24(1) The presiding officer shall rule on admissibility of evidence and may, where appropriate, take official notice of facts in accordance with all applicable requirements of law.

69.24(2) Stipulation of facts is encouraged. The presiding officer may make a decision based on stipulated facts.

69.24(3) Evidence in the proceeding shall be confined to the contested issues as identified in the notice of hearing.

69.24(4) The party seeking admission of an exhibit must provide opposing parties with an opportunity to examine the exhibit prior to the ruling on its admissibility. Copies of documents should normally be provided to opposing parties. All exhibits admitted into evidence shall be appropriately marked and be made part of the record.

69.24(5) Any party may object to specific evidence or may request limits on the scope of any examination or cross-examination. Such an objection shall be accompanied by a brief statement of the grounds upon which it is based. The objection, the ruling on the objection, and the reasons for the ruling shall be noted in the record. The presiding officer may rule on the objection at the time it is made or may reserve a ruling until the written decision.

69.24(6) Whenever evidence is ruled inadmissible, the party offering that evidence may submit an offer of proof on the record. The party making the offer of proof for excluded oral testimony shall briefly summarize the testimony or, with permission of the presiding officer, present the testimony. If the excluded evidence consists of a document or exhibit, it shall be marked as part of an offer of proof and inserted in the record.

875—69.25(17A,89A) Ex parte communication.

69.25(1) Prohibited communications. Unless required for the disposition of ex parte matters specifically authorized by statute, following issuance of the notice of hearing, there shall be no communication, directly or indirectly, between the presiding officer and any party or representative of any party or any other person with a direct or indirect interest in such case in connection with any issue of fact or law in the case except upon notice and opportunity for all parties to participate. Nothing in this rule is intended to preclude board members from communicating with other board members or members of the board staff, other than those with a personal interest in, or those engaged in personally investigating, prosecuting, or advocating in, either the case under consideration or a pending factually related case involving the same parties, as long as those persons do not directly or indirectly communicate to the presiding officer any ex parte communications they have received of a type that the presiding officer would be prohibited from receiving or that furnish, augment, diminish, or modify the evidence in the record.

69.25(2) Prohibitions on ex parte communications commence with the issuance of the notice of hearing in a contested case and continue for as long as the case is pending before the board.

69.25(3) Written, oral or other forms of communication are "ex parte" if made without notice and opportunity for all parties to participate.

69.25(4) To avoid prohibited ex parte communications, notice must be given in a manner reasonably calculated to give all parties a fair opportunity to participate. Notice of written communications shall be provided and may be supplemented by telephone, facsimile, electronic mail or other means of

notification. Where permitted, oral communications may be initiated through conference telephone call including all parties or their representatives.

69.25(5) Persons who jointly act as presiding officer in a pending contested case may communicate with each other without notice or opportunity for parties to participate.

69.25(6) Communications with the presiding officer involving uncontested scheduling or procedural matters do not require notice or opportunity for parties to participate. Parties should notify other parties prior to initiating such contact with the presiding officer when feasible, and shall notify other parties when seeking to continue hearings or other deadlines.

a. If the presiding officer determines that disqualification is warranted, the following shall be submitted for inclusion in the record under seal by protective order:

(1) A copy of any prohibited written communication,

(2) All written responses to the communication,

(3) A written summary stating the substance of any prohibited oral or other communication not available in written form and all responses made, and

(4) The identity of each person from whom the presiding officer received a prohibited ex parte communication; or

b. If the presiding officer determines that disqualification is not warranted, such documents shall be submitted for inclusion in the record and served on all parties. Any party desiring to rebut the prohibited communication must be allowed the opportunity to do so upon written request filed within ten days after notice of the communication.

69.25(7) Promptly after being assigned to serve as presiding officer at any stage in a contested case proceeding, a presiding officer shall disclose to all parties material factual information received through ex parte communication prior to such assignment, unless the factual information has already been or shortly will be disclosed pursuant to Iowa Code section 17A.13, subsection 2, or through discovery. Factual information contained in an investigative report or similar document need not be separately disclosed by the presiding officer as long as such documents have been or will shortly be provided to the parties.

69.25(8) The presiding officer may render a proposed or final decision imposing appropriate sanctions for violations of this rule. Violation of ex parte communication prohibitions by staff shall be reported to the board and to the commissioner.

[**ARC 8621B**, IAB 3/24/10, effective 4/28/10]

875—69.26(17A,89A) Interlocutory appeals.

69.26(1) Upon written request of a party or on its own motion, the board may review an interlocutory order of the administrative law judge. In determining whether to do so, the board shall weigh the extent to which its granting the interlocutory appeal would expedite final resolution of the case and the extent to which review of the interlocutory order at the time of the issuance of a final decision would provide an adequate remedy.

69.26(2) Any request for interlocutory review under this rule must be filed within 14 days of issuance of the challenged order, but no later than the date for compliance with the order or the date of hearing, whichever is earlier.

69.26(3) This rule does not apply to the ruling of an administrative law judge after hearing on a motion to quash or modify a subpoena. The procedures for challenging such a ruling are set forth in subrule 69.17(7).

[**ARC 0168C**, IAB 6/13/12, effective 7/18/12]

875—69.27(17A,89A) Decisions.

69.27(1) *Proposed decision.* Decisions issued by a panel of less than a quorum of the board or by an administrative law judge are proposed decisions. A proposed decision issued by a panel of the board or an administrative law judge becomes a final decision if not timely appealed by any party or reviewed by the board.

69.27(2) *Final decision.* When a quorum of the board presides over the reception of evidence at the hearing, the decision is a final decision. A copy of the final decision and order shall immediately be sent

by certified mail to the appellant's last-known post office address or may be served as in the manner of original notices. Copies shall be mailed by interoffice mail or first-class mail to the counsel of record.

69.27(3) *Appeals and review.*

a. Appeal by party. Any adversely affected party may appeal a proposed decision to the board within 30 days after issuance of the proposed decision.

b. Review. The board may initiate review of a proposed decision on its own motion at any time within 30 days following the issuance of such a decision.

c. Notice of appeal. An appeal of a proposed decision is initiated by filing a timely notice of appeal with the board. The notice of appeal must be signed by the appealing party or a representative of that party and contain a certificate of service. The notice shall specify:

(1) The parties initiating the appeal;

(2) The proposed decision or order appealed from;

(3) The specific findings or conclusions to which exception is taken and any other exceptions to the decision or order;

(4) The relief sought;

(5) The grounds for relief.

d. Requests to present additional evidence. A party may request the taking of additional evidence only by establishing that the evidence is material, that good cause existed for the failure to present the evidence at the hearing, and that the party has not waived the right to present the evidence. A written request to present additional evidence must be filed with the notice of appeal or, by a nonappealing party, within 14 days of service of the notice of appeal. The board may remand a case to the presiding officer for further hearing or may itself preside at the taking of additional evidence.

e. Scheduling. The board shall issue a schedule for consideration of the appeal.

f. Briefs and arguments. Unless otherwise ordered, within 20 days of the notice of appeal or order for review, each appealing party may file exceptions and briefs. Within 20 days thereafter, any party may file a responsive brief. Briefs shall cite any applicable legal authority and specify relevant portions of the record in that proceeding. Written requests to present oral argument shall be filed with the briefs.

The board may resolve the appeal on the briefs or provide an opportunity for oral argument. The board may shorten or extend the briefing period as appropriate.

g. Record. The record on appeal or review shall be the entire record made before the hearing panel or administrative law judge.

875—69.28(17A,89A) Contested cases with no factual disputes. If the parties agree that no dispute of material fact exists as to a matter that would be a contested case if such a dispute of fact existed, the parties may present all relevant admissible evidence either by stipulation or otherwise as agreed by the parties without necessity for the production of evidence at an evidentiary hearing. If such agreement is reached, a jointly submitted schedule detailing the method and timetable for submission of the record, briefs and oral argument should be submitted to the presiding officer for approval as soon as practicable. If the parties cannot agree, any party may file and serve a motion for summary judgment pursuant to the rules governing such motions.

875—69.29(17A,89A) Applications for rehearing.

69.29(1) *By whom filed.* Any party to a contested case proceeding may file an application for rehearing from a final order.

69.29(2) *Content of application.* The application for rehearing shall state on whose behalf it is filed, the specific grounds for rehearing, and the relief sought.

69.29(3) *Time of filing.* The application shall be filed with the board within 20 days after issuance of the final decision.

69.29(4) *Notice to other parties.* A copy of the application shall be timely mailed by the applicant to all parties of record not joining therein.

69.29(5) *Disposition.* The board may meet telephonically to consider an application for rehearing. Any application for a rehearing shall be deemed denied unless the board grants the application within 20 days after its filing.

875—69.30(17A,89A) Stays of board actions.

69.30(1) *When available.*

a. Any party to a contested case proceeding may petition the board for a stay of an order issued in that proceeding or for other temporary remedies, pending review by the board. The petition shall be filed with the notice of appeal and shall state the reasons justifying a stay or other temporary remedy. The board may rule on the stay or authorize the administrative law judge to do so.

b. Any party to a contested case proceeding may petition the board for a stay or other temporary remedies, pending judicial review of all or part of that proceeding. The petition shall state the reasons justifying a stay or other temporary remedy.

69.30(2) *When granted.* In determining whether to grant a stay, the presiding officer or board shall consider the factors listed in Iowa Code section 17A.19(5)*"c."*

69.30(3) *Vacation.* A stay may be vacated by the issuing authority upon application of the board or any other party.

875—69.31(17A,89A) Judicial review. Judicial review of the board's decision may be sought in accordance with the terms of Iowa Code chapter 17A.

69.31(1) Consistent with Iowa Code section 17A.19(3), if a party does not file a timely application for rehearing, a judicial review petition must be filed with the district court within 30 days after the issuance of the board's final decision. The board's final decision is deemed issued on the date it is mailed or the date of delivery if service is by other means, unless another date is specified in the order.

69.31(2) If a party does file a timely application for rehearing, a judicial review petition must be filed with the district court within 30 days after the application for rehearing is denied or deemed denied. An application for rehearing is denied or deemed denied as provided in subrule 69.29(5).

These rules are intended to implement Iowa Code chapters 17A and 89A.

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CHAPTER 70
PUBLIC RECORDS AND FAIR INFORMATION PRACTICES OF THE ELEVATOR SAFETY BOARD

875—70.1(22,89A) Definitions. As used in this chapter:

"Confidential record" in these rules means a record which is not available as a matter of right for examination and copying by members of the public under applicable provisions of law. Confidential records include records or information contained in records that the board is prohibited by law from making available for examination by members of the public, and records or information contained in records that are specified as confidential by Iowa Code section 22.7, or other provision of law, but that may be disclosed upon order of a court, the lawful custodian of the record, or by another person duly authorized to release the record. Mere inclusion in a record of information declared confidential by an applicable provision of law does not necessarily make that entire record a confidential record.

"Custodian" in these rules means the elevator safety board.

"Personally identifiable information" in these rules means information about or pertaining to an individual in a record which identifies the individual and which is contained in a record system.

"Record" in these rules means the whole or a part of a "public record," as defined in Iowa Code section 22.1, that is owned by or in the physical possession of the board.

"Record system" in these rules means any group of records under the control of the board from which a record may be retrieved by a personal identifier such as the name of an individual, number, symbol, or other unique retriever assigned to an individual.

[**ARC 8621B**, IAB 3/24/10, effective 4/28/10]

875—70.2(22,89A) Statement of policy. The purpose of this chapter is to facilitate broad public access to open records and sound board determinations with respect to the handling of confidential records and the implementation of the fair information practices Act. The board is committed to the policies set forth in Iowa Code chapter 22; the board shall cooperate with members of the public in implementing the provisions of that chapter.

[**ARC 8621B**, IAB 3/24/10, effective 4/28/10]

875—70.3(22,89A) Requests for access to records.

70.3(1) *Address.* The board's mailing address is Department of Workforce Development, Division of Labor Services, 1000 East Grand Avenue, Des Moines, Iowa 50319. The board's staff is located at 150 Des Moines Street, Des Moines, Iowa.

70.3(2) *Office hours.* Open records shall be made available during all customary office hours, which are 8 a.m. to 4:30 p.m., Monday through Friday.

70.3(3) *Request for access.* Requests for access to open records may be made in writing, in person, by facsimile, E-mail, or other electronic means, or by telephone. Requests shall identify the particular records sought by name or description in order to facilitate the location of the record. Mail, electronic, or telephone requests shall include the name, address, and telephone number of the person requesting the information to facilitate the board's response. A person shall not be required to give a reason for requesting an open record. While agencies are not required by Iowa Code chapter 22 to respond to requests for public records that are not made in person, the board will respond to such requests as reasonable under the circumstances.

70.3(4) *Response to requests.* Access to an open record shall be provided promptly upon request unless the size or nature of the request makes prompt access infeasible. If the size or nature of the request for access to an open record requires time for compliance, the custodian shall comply with the request as soon as feasible. Access to an open record may be delayed for one of the purposes authorized by Iowa Code section 22.8(4) or 22.10(4). The custodian shall promptly give notice to the requester of the reason for any delay in access to an open record and an estimate of the length of that delay and, upon request, shall promptly provide that notice to the requester in writing.

The custodian of a record may deny access to the record by members of the public only on the grounds that such a denial is warranted under Iowa Code sections 22.8(4) and 22.10(4), or that it is a

confidential record, or that its disclosure is prohibited by a court order. Access by members of the public to a confidential record is limited by law and, therefore, may generally be provided only in accordance with the provisions of rule 875—70.4(22,89A) and other applicable provisions of law.

70.3(5) *Security of record.* No person may, without permission from the custodian, search or remove any record from board files. Examination and copying of board records shall be supervised by the custodian or a designee of the custodian. Records shall be protected from damage and disorganization.

70.3(6) *Copying.* A reasonable number of copies of an open record may be made in the board's office. If photocopy equipment is not available in the board office where an open record is kept, the custodian shall permit its examination in that office and shall arrange to have copies promptly made elsewhere.

70.3(7) *Fees.*

a. When charged. The board may charge fees in connection with the examination or copying of records only if the fees are authorized by law. To the extent permitted by applicable provisions of law, the payment of fees may be waived when the imposition of fees is inequitable or when a waiver is in the public interest.

b. Copying and postage costs. Price schedules for published materials and for photocopies of records supplied by the board shall be prominently posted in board offices. Copies of records may be made by or for members of the public on board photocopy machines or from electronic storage systems at cost as determined and posted in board offices by the custodian. When the mailing of copies of records is requested, the actual costs of such mailing may also be charged to the requester.

c. Supervisory fee. An hourly fee may be charged for actual board expenses in supervising the examination and copying of requested records when the supervision time required is in excess of 15 minutes. The custodian shall prominently post in board offices the hourly fees to be charged for supervision of records during examination and copying. The hourly fee shall be based upon the pay scale of the employee involved and other actual costs incurred. To the extent permitted by law, a search fee may be charged at the same rate as and under the same conditions as are applicable to supervisory fees.

d. Advance deposits.

(1) When the estimated total fee chargeable under this subrule exceeds $25, the custodian may require a requester to make an advance payment to cover all or a part of the estimated fee.

(2) When a requester has previously failed to pay a fee chargeable under this subrule, the custodian may require advance payment of the full amount of any estimated fee before the custodian processes a new request from that requester.

[**ARC 8621B**, IAB 3/24/10, effective 4/28/10; **ARC 3856C**, IAB 6/20/18, effective 8/1/18]

875—70.4(22,89A) Access to confidential records. Under Iowa Code section 22.7 or other applicable provisions of law, the lawful custodian may disclose certain confidential records to one or more members of the public. Other provisions of law authorize or require the custodian to release specified confidential records under certain circumstances or to particular persons. In requesting the custodian to permit the examination and copying of such a confidential record, the following procedures apply and are in addition to those specified for requests for access to records in rule 875—70.3(22,89A).

70.4(1) *Proof of identity.* A person requesting access to a confidential record may be required to provide proof of identity or authority to secure access to the record.

70.4(2) *Requests.* The custodian may require a request to examine and copy a confidential record to be in writing. A person requesting access to such a record may be required to sign a certified statement or affidavit enumerating the specific reasons justifying access to the confidential record and to provide any proof necessary to establish relevant facts.

70.4(3) *Notice to subject of record and opportunity to obtain injunction.* After the custodian receives a request for access to a confidential record, and before the custodian releases such a record, the custodian may make reasonable efforts to notify promptly any person who is a subject of that record, is identified in that record, and whose address or telephone number is contained in that record. To the extent such a delay is practicable and in the public interest, the custodian may give the subject of such a confidential

record to whom notification is transmitted a reasonable opportunity to seek an injunction under Iowa Code section 22.8, and indicate to the subject of the record the specific period of time during which disclosure will be delayed for that purpose.

70.4(4) *Request denied.* When the custodian denies a request for access to a confidential record, the custodian shall promptly notify the requester. If the requester indicates to the custodian that a written notification of the denial is desired, the custodian shall promptly provide such a notification that is signed by the custodian and that includes:

a. The name and title or position of the custodian responsible for the denial; and

b. A citation to the provision of law vesting authority in the custodian to deny disclosure of the record and a brief statement of the reasons for the denial to this requester.

70.4(5) *Request granted.* When the custodian grants a request for access to a confidential record to a particular person, the custodian shall notify that person and indicate any lawful restrictions imposed by the custodian on that person's examination and copying of the record.

875—70.5(22,89A) Requests for treatment of a record as a confidential record and its withholding from examination. The custodian may treat a record as a confidential record and withhold it from examination only to the extent that the custodian is authorized by Iowa Code section 22.7, another applicable provision of law, or a court order to refuse to disclose that record to members of the public.

70.5(1) *Persons who may request.* Any person who would be aggrieved or adversely affected by disclosure of a record and who asserts that Iowa Code section 22.7, another applicable provision of law, or a court order authorizes the custodian to treat the record as a confidential record may request the custodian to treat that record as a confidential record and to withhold it from public inspection.

70.5(2) *Request.* A request that a record be treated as a confidential record and be withheld from public inspection shall be in writing and shall be filed with the custodian. The request must set forth the legal and factual basis justifying such confidential record treatment for that record, and the name, address, and telephone number of the person authorized to respond to any inquiry or action of the custodian concerning the request. A person requesting treatment of a record as a confidential record may also be required to sign a certified statement or affidavit enumerating the specific reasons justifying the treatment of that record as a confidential record and to provide any proof necessary to establish relevant facts. Requests for treatment of a record as a confidential record for a limited time period shall also specify the precise period of time for which that treatment is requested.

A person filing such a request shall, if possible, accompany the request with a copy of the record in question with those portions deleted for which such confidential record treatment has been requested. If the original record is being submitted to the board by the person requesting such confidential treatment at the time the request is filed, the person shall indicate conspicuously on the original record that all or portions of it are confidential.

70.5(3) *Failure to request.* Failure of a person to request confidential record treatment for a record does not preclude the custodian from treating it as a confidential record. However, if a person who has submitted business information to the board does not request that it be withheld from public inspection under Iowa Code sections 22.7(3) and 22.7(6), the custodian of records containing that information may proceed as if that person has no objection to its disclosure to members of the public.

70.5(4) *Timing of decision.* A decision by the custodian with respect to the disclosure of a record to members of the public may be made when a request for its treatment as a confidential record that is not available for public inspection is filed, or when the custodian receives a request for access to the record by a member of the public.

70.5(5) *Request granted or deferred.* If a request for confidential record treatment is granted, or if action on such a request is deferred, a copy of the record from which the matter in question has been deleted and a copy of the decision to grant the request or to defer action upon the request will be made available for public inspection in lieu of the original record. If the custodian subsequently receives a request for access to the original record, the custodian will make reasonable and timely efforts to notify any person who has filed a request for its treatment as a confidential record that is not available for public inspection of the pendency of that subsequent request.

70.5(6) *Request denied and opportunity to seek injunction.* If a request that a record be treated as a confidential record and be withheld from public inspection is denied, the custodian shall notify the requester in writing of that determination and the reasons therefor. On application by the requester, the custodian may engage in a good-faith, reasonable delay in allowing examination of the record so that the requester may seek injunctive relief under the provisions of Iowa Code section 22.8, or other applicable provision of law. However, such a record shall not be withheld from public inspection for any period of time if the custodian determines that the requester had no reasonable grounds to justify the treatment of that record as a confidential record. The custodian shall notify requester in writing of the time period allowed to seek injunctive relief or the reasons for the determination that no reasonable grounds exist to justify the treatment of that record as a confidential record. The custodian may extend the period of good-faith, reasonable delay in allowing examination of the record so that the requester may seek injunctive relief only if no request for examination of that record has been received, or if a court directs the custodian to treat it as a confidential record, or to the extent permitted by another applicable provision of law, or with the consent of the person requesting access.
[**ARC 8621B**, IAB 3/24/10, effective 4/28/10]

875—70.6(22,89A) Procedure by which additions, dissents, or objections may be entered into certain records. Except as otherwise provided by law, a person may file a request with the custodian to review, and to have a written statement of additions, dissents, or objections entered into, a record containing personally identifiable information pertaining to that person. However, this does not authorize a person who is a subject of such a record to alter the original copy of that record or to expand the official record of any board proceeding. Requester shall send the request to review such a record or the written statement of additions, dissents, or objections to the board at the Department of Workforce Development, Division of Labor Services, 1000 East Grand Avenue, Des Moines, Iowa 50319. The request to review such a record or the written statement of such a record of additions, dissents, or objections must be dated and signed by requester, and shall include the current address and telephone number of the requester or the requester's representative.
[**ARC 8621B**, IAB 3/24/10, effective 4/28/10]

875—70.7(22,89A) Consent to disclosure by the subject of a confidential record. To the extent permitted by any applicable provision of law, a person who is the subject of a confidential record may have a copy of the portion of that record concerning the subject disclosed to a third party. A request for such a disclosure must be in writing and must identify the particular record or records that may be disclosed, and the particular person or class of persons to whom the record may be disclosed and, where applicable, the time period during which the record may be disclosed. The person who is the subject of the record and, where applicable, the person to whom the record is to be disclosed, may be required to provide proof of identity. Additional requirements may be necessary for special classes of records. Appearance of an attorney before the board on behalf of a person who is the subject of a confidential record is deemed to constitute consent for the board to disclose records about that person to the person's attorney.
[**ARC 8621B**, IAB 3/24/10, effective 4/28/10]

875—70.8(22,89A) Disclosures without the consent of the subject.

70.8(1) Open records are routinely disclosed without the consent of the subject.

70.8(2) To the extent allowed by law, disclosure of confidential records may occur without the consent of the subject. Following are instances where disclosure, if lawful, will generally occur without notice to the subject:

a. For a routine use as defined in rule 875—70.9(17A, 89A) or in the notice for a particular record system.

b. To a recipient who has provided the board with advance written assurance that the record will be used solely as a statistical research or reporting record, provided that the record is transferred in a form that does not identify the subject.

c. To another government agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if an authorized representative of such government agency or instrumentality has submitted a written request to the board specifying the record desired and the law enforcement activity for which the record is sought.

d. To an individual pursuant to a showing of compelling circumstances affecting the health or safety of any individual if a notice of the disclosure is transmitted to the last-known address of the subject.

e. To the legislative services agency.

f. Disclosures in the course of employee disciplinary proceedings.

g. In response to a court order or subpoena.

[**ARC 8621B**, IAB 3/24/10, effective 4/28/10]

875—70.9(17A,89A) Routine use. "Routine use" means the disclosure of a record without the consent of the subject or subjects for a purpose which is compatible with the purpose for which the record was collected. "Routine use" includes disclosures required to be made by statute other than the public records law, Iowa Code chapter 22. To the extent allowed by law, the following uses are considered routine uses of all board records:

70.9(1) Disclosure to those officers, employees, and agents of the board who have a need for the record in the performance of their duties. The custodian of the record may, upon request of any officer or employee, or on the custodian's own initiative, determine what constitutes a legitimate need to use confidential records.

70.9(2) Disclosure of information indicating an apparent violation of the law to appropriate law enforcement authorities for investigation and possible criminal prosecution, civil court action, or regulatory order.

70.9(3) Disclosure to the department of inspections and appeals for matters in which it is performing services or functions on behalf of the board.

70.9(4) Transfers of information within the board, to other state agencies, or to local units of government as appropriate to administer the program for which the information is collected.

70.9(5) Information released to staff of federal and state entities for audit purposes or for purposes of determining whether the board is operating a program lawfully.

70.9(6) Any disclosure specifically authorized by the statute under which the record was collected or maintained.

70.9(7) Disclosure to the public and news media of pleadings, motions, orders, final decisions, and informal settlement filed in appeal proceedings.

70.9(8) Transmittal to the district court of the record in judicial review proceedings pursuant to Iowa Code section 17A.19.

[**ARC 8621B**, IAB 3/24/10, effective 4/28/10]

875—70.10(22,89A) Consensual disclosure of confidential records.

70.10(1) *Consent to disclosure by a subject individual.* To the extent permitted by law, the subject may consent in writing to board disclosure of confidential records as provided in rule 875—70.7(22,89A).

70.10(2) *Complaints to public officials.* A letter from a subject of a confidential record to a public official which seeks the official's intervention on behalf of the subject in a matter that involves the board may, to the extent permitted by law, be treated as an authorization to release sufficient information about the subject to the official to resolve the matter.

875—70.11(22,89A) Release to subject.

70.11(1) The subject of a confidential record may file a written request to review confidential records about that person. However, the board need not release the following records to the subject:

a. The identity of a person providing information to the board need not be disclosed directly or indirectly to the subject of the information when the information is authorized to be held confidential pursuant to Iowa Code section 22.7(18) or other provision of law.

b. Records need not be disclosed to the subject when they are the work product of an attorney or are otherwise privileged.

c. Peace officers' investigative reports may be withheld from the subject, except as required by the Iowa Code. (Iowa Code section 22.7(5))

d. Other records may be withheld from the subject as authorized by law.

70.11(2) When a record has multiple subjects with interest in the confidentiality of the record, the board may take reasonable steps to protect confidential information relating to another subject.
[**ARC 8621B**, IAB 3/24/10, effective 4/28/10]

875—70.12(21,22,89A) Availability of records.

70.12(1) *General.* Board records are open for public inspection and copying unless otherwise provided by rule or law.

70.12(2) *Confidential records.* The following records may be withheld from public inspection. Records are listed by category, according to the legal basis for withholding them from public inspection.

a. Personal information in confidential personnel records of board members and licensees. (Iowa Code section 22.7(11))

b. Minutes and tapes of closed meetings of the board. (Iowa Code section 21.5(4))

c. Information or records received from a restricted source and any other information or records made confidential by law.

d. Records which constitute attorney work products or attorney-client communications or which are otherwise privileged pursuant to Iowa Code section 22.7, 622.10 or 622.11, state and federal rules of evidence or procedure, the Code of Professional Responsibility, and case law.

e. Identifying details in final orders, decisions and opinions to the extent required to prevent a clearly unwarranted invasion of personal privacy or trade secrets under Iowa Code section 17A.3(1)*"e."*

70.12(3) *Authority to release confidential records.* The board may have discretion to disclose some confidential records which are exempt from disclosure under Iowa Code section 22.7 or other law. Any person may request permission to inspect records withheld from inspection under a statute which authorizes limited or discretionary disclosure as provided in rule 875—70.4(22,89). If the board initially determines that it will release such records, the board may, where appropriate, notify interested parties and withhold the records from inspection as provided in subrule 70.4(3).
[**ARC 8621B**, IAB 3/24/10, effective 4/28/10]

875—70.13(22,89A) Applicability. This chapter does not:

70.13(1) Require the board to index or retrieve records that contain information about individuals by a person's name or other personal identifier.

70.13(2) Make available to the general public records that would otherwise not be available under the public records law, Iowa Code chapter 22.

70.13(3) Govern the maintenance or disclosure of, notification of, or access to records in the possession of the board that are governed by the regulations of another agency.

70.13(4) Apply to grantees, including local governments or subdivisions thereof, administering state-funded programs, unless otherwise provided by law or agreement.

70.13(5) Make available records compiled by the board in reasonable anticipation of court litigation or formal administrative proceedings. The availability of such records to the general public or to any subject individual or party to such litigation or proceedings shall be governed by applicable legal and constitutional principles, statutes, rules of discovery, evidentiary privileges, and applicable rules of the board.
[**ARC 8621B**, IAB 3/24/10, effective 4/28/10]

875—70.14(17A,22,89A) Personally identifiable information. This rule describes the nature and extent of personally identifiable information which is collected, maintained, and retrieved by the board by personal identifier in record systems. For each record system, this rule describes the legal authority for the collection of that information. The record systems maintained by the board are:

70.14(1) *Personnel records.* These records contain personal information about board members which may be confidential pursuant to Iowa Code section 22.7(11). The records may include but are not limited to biographical information, medical information relating to disability, and information required for expense reimbursement.

70.14(2) *Contested case records.* Contested case records are maintained and contain names of the people involved. Evidence and documents submitted as a result of a hearing are contained in the contested case records. These records are collected pursuant to Iowa Code section 89A.11.
[**ARC 8621B**, IAB 3/24/10, effective 4/28/10]

875—70.15(17A,21,22,89A) Other groups of records. This rule describes groups of records maintained by the board other than record systems. These records are routinely available to the public. However, the board's files of these records may contain confidential information. These records may contain information about individuals. These records include:

70.15(1) *Rule-making records.* Rule-making records may contain information about individuals making written or oral comments on proposed rules. This information is collected pursuant to Iowa Code section 17A.4. These records are stored on paper and electronically.

70.15(2) *Board records.* Agendas, minutes, and materials presented to the board members in preparation for board meetings are available from the board office, except those records concerning closed sessions which are exempt from disclosure under Iowa Code section 21.5(4). Board records contain information about people who participate in meetings. This information is collected pursuant to Iowa Code section 21.3. This information is stored on paper and electronically.

70.15(3) *Board decisions, findings of fact, final orders, and other statements of law, policy, or declaratory orders issued by the board in the performance of its functions.* These records are open to the public except for information that is confidential according to rule 875—70.12(21,22,89A). This information is stored on paper and electronically.

70.15(4) *Waivers and variances.* Requests for waivers and variances, board proceedings and rulings on such requests, and reports prepared for the administrative rules review committee and others are stored on paper and electronically.

70.15(5) *Publications.* News releases, project reports, newsletters, and other publications are available from the board office. These records may contain information about individuals. This information is stored on paper and electronically, and some publications may be found on the board's Web site.

70.15(6) *Other records.* Other records that are not exempted from disclosure by law may be stored on paper or electronically.
[**ARC 8621B**, IAB 3/24/10, effective 4/28/10]

875—70.16(22,89A) Data processing system. Board records are not stored in a data processing system which matches, collates, or permits comparison of personally identifiable information in one record system with personally identifiable information in another record system.

875—70.17(22,89A) Notice to suppliers of information. Persons that are requested by the board to provide information to the board are notified pursuant to this rule of uses the board will make of the information.

70.17(1) The board may request names and affiliations from members of the public that attend board meetings. Except for closed sessions, the records of board meetings are public records and information supplied will be subject to records requests pursuant to this chapter and Iowa Code chapter 22. Provision of this information is voluntary, and there will be no consequences for failure to provide requested information unless the person is also covered by subrule 70.17(2).

70.17(2) The board will request name, contact information, and affiliation from persons requesting board action. This information will be used as needed to process the request for board action. Requests for board action are public records, and information supplied will be subject to open records requests

pursuant to this chapter and Iowa Code chapter 22. Insufficient contact information provided with the request for board action could result in a denial of the request for board action.

These rules are intended to implement Iowa Code chapters 17A, 21, 22 and 89A.

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CHAPTER 71
ADMINISTRATION OF THE CONVEYANCE SAFETY PROGRAM

875—71.1(89A) Definitions. The definitions contained in this rule shall apply to 875—Chapters 71, 72, and 73.

"Acceptance checklist" means a checklist available on the website of the division of labor services that includes a list of major systems and components of conveyances.

"AECO" means an elevator/escalator certification organization accredited pursuant to ASME A17.7.

"Approved" means approved by the division.

"CCD" means code compliance documentation as described in ASME A17.7, Section 2.10.

"CEI" means a person who is a certified elevator inspector or certified elevator inspector supervisor and who received the certification from a certifying organization that holds a valid document of accreditation issued by an accreditation body in accordance with ANSI/ISO/IEC 17024.

"Control" means the system governing the starting, stopping, direction of motion, acceleration, speed and deceleration of the moving member.

"Conveyance" means any elevator, escalator, material lift elevator installed on or after August 10, 2016, dumbwaiter, wind tower lift, CPH, or other equipment governed by Iowa Code chapter 89A.

"CPH" means a construction personnel hoist.

"CPH jump" means the addition or removal of mast or tower allowing a change in the hoist service elevation of a CPH.

"Division" means the labor services division of the workforce development department.

"Elevator" means a hoisting and lowering mechanism equipped with a car or platform which moves in guides in a substantially vertical direction and which serves two or more floors of a building or structure. "Elevator" does not include a CPH.

"Elevator mechanic" means a person who meets the standard for "elevator personnel" found in ASME A17.1.

"Hoistway-unit system" means a series of hoistway-door interlocks, hoistway-door electric contacts or hoistway-door combination mechanical locks and electric contacts, or a combination thereof, the function of which is to prevent operation of the driving machine by the normal operating device unless all hoistway doors are in the closed position and, if required, locked.

"Wind tower lift" means a conveyance designed and utilized solely for movement of trained and authorized people and small loads in wind towers built for the production of electricity.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09; **ARC 9221B**, IAB 11/17/10, effective 12/22/10; **ARC 0168C**, IAB 6/13/12, effective 7/18/12; **ARC 0685C**, IAB 4/17/13, effective 5/22/13; **ARC 1159C**, IAB 10/30/13, effective 12/4/13; **ARC 2603C**, IAB 7/6/16, effective 8/10/16]

875—71.2(89A) Registration of conveyances. The owner or authorized agent of each operable conveyance not previously registered shall register the conveyance. An application to install a new conveyance shall constitute registration. All registrations shall be submitted to the commissioner on forms available from the division of labor services and shall include all information requested by the labor commissioner.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09]

875—71.3(89A) State identification number. The commissioner shall assign an identification number to each conveyance that shall be stamped on a metal tag permanently attached to the controller, to the electrical disconnecting switch, or in a wind tower lift cage.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09]

875—71.4(89A) Responsibility for obtaining permits. The procuring of all permits and the payment of all fees required by this chapter shall be the responsibility of the owner. Failure to obtain the appropriate permit prior to installation, alteration or operation may, at the discretion of the labor commissioner, result in a referral to the attorney general for prosecution of criminal penalties as described in Iowa Code section 89A.17.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09]

875—71.5(89A) Installation permits.

71.5(1) Installation shall not begin until an installation permit has been issued by the division. A separate installation permit shall be issued for each conveyance, except that a single installation permit shall cover all identical wind tower lifts installed as the result of one construction contract in identical wind towers in a single wind farm.

71.5(2) Application for an installation permit shall be accompanied by the fee specified in rule 875—71.16(89A), shall be in the format required by the labor commissioner, and shall include the following, as applicable:

a. Sectional plan of car and hoistway.

b. Sectional plan of machine room.

c. Sectional elevation of hoistway and machine room including the pit, bottom and top clearance of car and counterweights.

d. Size and weight of rails and guide rail bracket spacing.

e. The estimated maximum vertical forces on the guide rails on application of the safety device.

f. In the case of freight elevators for class B or class C loading, the horizontal forces on the guide rail faces during loading and unloading and the estimated maximum horizontal forces in a post-wise direction on the guide rail faces on the application of the safety device.

g. The size and weight per foot of any rail reinforcements where rail reinforcements are provided.

h. Job specifications.

i. For a conveyance covered by ASME A17.7, a complete copy of the CCD with attachments and a complete copy of the Certificate of Conformance with attachments as described by ASME A17.7, Appendix I, Section 4.5.

j. For a CPH, the number of CPH jumps planned, the planned dates for each CPH jump, and the change in the number of floors anticipated with each CPH jump.

71.5(3) A CPH installation permit issued in response to an application submitted in full compliance with this subrule permits each planned CPH jump. Each CPH jump shall be considered an alteration. The fee submitted for a CPH installation permit shall be the total of the CPH installation permit fee as set forth in subrule 71.16(3) and the CPH alteration permit fee as set forth in subrule 71.16(4).

71.5(4) Issuance of an installation permit shall not be construed as a waiver or variance of any requirement of law.

71.5(5) The installation permit or a copy of the installation permit shall be conspicuously posted at the worksite. All the wind towers covered by a single installation permit shall be considered a single worksite, and posting one copy of the installation permit at the construction project office shall be sufficient compliance with this subrule.

71.5(6) Except as described in paragraphs 71.5(6)*"a"* and *"b,"* the installation permit shall expire upon the earlier of the completion of the installation as described in the permit application or one year after issuance.

a. For a CPH, the installation permit shall expire upon completion of the last CPH jump.

b. For any conveyance, during the tenth month after issuance, and upon submission to the labor commissioner of sufficient justification, the fee established by this chapter, and other required information, an extension may be granted at the discretion of the labor commissioner.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09; **ARC 9221B**, IAB 11/17/10, effective 12/22/10]

875—71.6(89A) Construction permits. A construction permit authorizes the temporary, limited use of an elevator for purposes relating to construction or demolition.

71.6(1) Use of the elevator shall not begin until a construction permit has been issued by the division.

71.6(2) Application for a construction permit shall be in the format required by the labor commissioner and must include all the information requested by the labor commissioner and the fee specified by this chapter.

71.6(3) Upon submission of the completed application and fee, a state inspector shall be scheduled to inspect the elevator. Construction permits shall be issued only if the following criteria are met:

a. The elevator has been successfully tested pursuant to the requirements of ASME A17.1, Section 8.11.5.13; and

b. The applicable requirements of ASME A17.1, Section 5.10, are met.

71.6(4) The construction permit or a copy of the construction permit shall be posted conspicuously in a protective sleeve in the elevator car.

71.6(5) The construction permit shall expire 120 days after issuance. However, between 90 and 110 days after issuance and upon submission to the labor commissioner of sufficient justification, the fee established by this chapter, and other required information, an extension of up to 90 days may be granted at the discretion of the labor commissioner.

71.6(6) Elevators with a construction permit but without an operating permit shall not be accessible to the general public.

71.6(7) Failure to comply with these provisions may result in the revocation of the construction permit.

71.6(8) An operating permit shall not be issued before construction and an acceptance inspection are complete.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09]

875—71.7(89A) Operating permits.

71.7(1) Operation of equipment covered by this chapter without a current operating permit is prohibited, except as authorized by rules 875—71.6(89A), 875—71.8(89A), and 875—71.20(89A). If operation of a conveyance is prohibited under this rule, the labor commissioner may post notice on the conveyance that it is not to be used. The conveyance may be returned to service only after an operating permit for the conveyance has been issued or reissued.

71.7(2) Operating permits shall not be issued prior to successful completion of an inspection pursuant to rule 875—71.11(89A) and payment of all permit and inspection fees owed to the division.

71.7(3) Current operating permits or copies of current operating permits shall be conspicuously displayed as follows:

a. The operating permit for an elevator or CPH shall be posted in the car.

b. The operating permit for an escalator, dumbwaiter, wind tower lift, moving walk, or wheelchair lift shall be posted on or near the subject conveyance.

71.7(4) An operating permit shall expire 60 days after the first permit renewal inspection following the issuance of the operating permit, unless an earlier date is dictated by this rule.

71.7(5) An operating permit is automatically suspended when an alteration begins. The operating permit automatically resumes when the elevator passes an inspection pursuant to rule 875—71.11(89A).

71.7(6) An operating permit is automatically terminated when an imminent danger notice is posted on the conveyance.

71.7(7) Notwithstanding other provisions of this rule, at the discretion of the labor commissioner, a temporary operating permit may be issued for up to 30 days provided the inspection has been completed and no code violations were identified. Issuance of a temporary operating permit does not extend the expiration date of the conveyance's operating permit.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09; **ARC 0318C**, IAB 9/5/12, effective 10/10/12; **ARC 0574C**, IAB 2/6/13, effective 3/13/13; **ARC 0685C**, IAB 4/17/13, effective 5/22/13]

875—71.8(89A) Controller upgrade permits. A controller upgrade permit may be issued to allow operation of an elevator while work to upgrade controls requires deactivation of the Phase I recall initiated by smoke sensing devices. Each elevator to be altered requires a separate controller upgrade permit. The duration of a controller upgrade permit shall not exceed 90 days. Each elevator in the group shall pass inspection pursuant to rule 875—71.11(89A) prior to being placed back into service.

71.8(1) A controller upgrade permit shall not be issued unless each of the following conditions is met:

a. Two or more elevators share a lobby at the level of the recall floor.

b. The project includes the installation of new elevator controllers in all of the elevators in the group.

c. Phase I fire recall initiated by a key-operated switch and all other controls shall be properly functioning for each elevator available for use.

d. There is a current alteration permit for the project.

e. A complete application for the controller upgrade permit and the fee established by this chapter have been submitted and accepted.

71.8(2) A controller upgrade permit shall not be construed to waive or excuse compliance with the requirements of any other governmental entity, including the department of public safety.

71.8(3) Upon the submission to the labor commissioner of sufficient justification, the fee established by this chapter, and other required information, an extension of the permit for up to 60 days may be granted.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09]

875—71.9(89A) Alteration permits.

71.9(1) Alteration shall not begin until an alteration permit has been issued by the division.

71.9(2) Application for an alteration permit shall be in the format required by the labor commissioner and shall include drawings and specifications of all planned changes and the fee specified by rule 875—71.16(89A).

71.9(3) Issuance of an alteration permit shall not be construed as a waiver or variance of any requirement of law.

71.9(4) The alteration permit or a copy of the alteration permit shall be conspicuously posted at the worksite.

71.9(5) If a complete installation permit application was submitted for a CPH pursuant to subrule 71.5(3), at least seven days' advance notice of each CPH jump shall be provided to the labor commissioner.

71.9(6) The alteration permit shall expire upon the earlier of the completion of the alteration as described in the permit application or one year after issuance. However, during the tenth month after issuance and upon submission to the labor commissioner of the fee set forth in this chapter, sufficient justification, and other required information, the labor commissioner may grant an extension of the alteration permit.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09; **ARC 9221B**, IAB 11/17/10, effective 12/22/10; **ARC 0685C**, IAB 4/17/13, effective 5/22/13; **ARC 2333C**, IAB 1/6/16, effective 2/10/16]

875—71.10(89A) Alterations.

71.10(1) Alterations or changes shall comply with rule 875—72.13(89A) or rule 875—73.8(89A), as applicable.

71.10(2) A conveyance that is relocated shall be brought into compliance with all codes that are applicable at the time of relocation.

71.10(3) Alterations of conveyances other than escalators and elevators shall require that the entire conveyance be brought into compliance with the current code.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09; **ARC 0168C**, IAB 6/13/12, effective 7/18/12; **ARC 0685C**, IAB 4/17/13, effective 5/22/13; **ARC 2396C**, IAB 2/17/16, effective 3/23/16]

875—71.11(89A) Inspections. Pursuant to Iowa Code section 89A.12, inspections by the labor commissioner's designee shall be permitted at reasonable times with or without prior notice.

71.11(1) *Scope of inspections.*

a. Comprehensive. Periodic inspections shall be comprehensive. Elevators being transferred from construction permits to operating permits, previously dormant conveyances being returned to service, relocated conveyances, and new conveyances shall be inspected in their entirety prior to operation.

b. Limited. The scope of an inspection after an alteration shall be determined by rule 875—72.13(89A) or 875—73.8(89A), as applicable. However, if the inspector notices a safety hazard in plain view outside the altered components, or if the periodic inspection is due, the entire conveyance shall be inspected.

71.11(2) *When inspections will occur.* When the timing of two different types of inspection on a single conveyance coincide, a state inspector may perform both inspections in one visit.

a. Periodic inspections.

(1) Each construction elevator and CPH shall be inspected at intervals not to exceed three months. All other periodic conveyance inspections by state inspectors shall be conducted annually unless the labor commissioner determines resources do not allow annual inspections. If the labor commissioner determines quarterly inspections of construction elevators and CPHs and annual inspections of other state-inspected conveyances are not feasible due to insufficient resources, the labor commissioner shall determine the inspection schedule.

(2) Conveyance inspections by special inspectors shall be conducted at least annually.

(3) The inspector shall arrange to perform the periodic inspection of a broadcast tower elevator when the maintenance company is on site to perform the periodic tests. If the inspection is to be performed by employees of the commissioner, the inspection shall occur during the division's normal business hours, unless otherwise agreed to by the commissioner pursuant to subrule 71.16(11).

b. Acceptance inspections. A CPH shall be inspected pursuant to the schedule in ANSI A10.4 – 2007, Chapter 26. For all other conveyances, an acceptance inspection shall occur:

(1) After each relocation,

(2) After each alteration,

(3) For a new installation, not less than two business days after a completed acceptance checklist is submitted by the conveyance installation company,

(4) Before an elevator subject to a construction permit receives an operating permit, and

(5) Before a previously dormant conveyance is returned to service.

c. Other inspections. Inspections may be made when the commissioner reasonably believes that a conveyance is not in compliance with the rules. Accidents, complaints, or requests for consultative inspections may result in inspections by the labor commissioner's designee.

71.11(3) *Who may perform inspections.*

a. The labor commissioner's designee shall inspect altered conveyances, construction elevators, CPHs, previously dormant conveyances being returned to service, relocated conveyances, and new conveyances.

b. Except as noted in 71.11(3)*"c,"* annual inspections may be performed by state inspectors or special inspectors authorized by the labor commissioner pursuant to rule 875—71.12(89A).

c. An inspection report by a special inspector shall not be accepted as the required, annual inspection if the conveyance is under contract for maintenance, installation or alteration by the special inspector or the special inspector's employer, or if the property is owned or leased by the special inspector or the special inspector's employer.

71.11(4) *Inspection standards.* Inspections shall be performed in accordance with applicable safety codes or documents such as:

a. CCD;

b. ASME A17.1, Sections 8.10 and 8.11, except Section 8.11.1.1;

c. ANSI A10.4-2007; or

d. ASME A18.1.

71.11(5) *Inspection reports.*

a. All inspectors shall file inspection reports on forms approved by the commissioner within 30 days from the date of inspection and shall provide owners of conveyances with copies of completed inspection reports. The inspection report must separately list each unsafe condition and the applicable, specific code citation. Up to 30 days shall be allowed for correction of the unsafe conditions.

b. The owner may file a petition for reconsideration of an inspection report pursuant to 875—Chapter 69. The timely and proper filing of a petition for reconsideration extends the deadline for correction of the hazards that are subject to the petition for reconsideration.

71.11(6) *Extension of time.* The owner may petition the commissioner for up to 60 additional days to make the necessary corrections. The time frames set forth in subrule 71.11(7) may be adjusted by the labor commissioner as necessary to accommodate an extension of time.

71.11(7) *Correction of unsafe conditions.* In the absence of a determination on reconsideration or appeal that correction of hazards is not required, all unsafe conditions identified in the inspection report

shall be corrected. The labor commissioner shall verify correction of all unsafe conditions identified in the inspection report by sending a state inspector to reinspect the conveyance for the fee set forth in rule 875—71.16(89A), or by reviewing appropriate documentation such as a photograph, invoice, other verifiable document, or subsequent inspection report. The time frames set forth in this subrule may be accelerated at the request of the owner.

a. Promptly upon receipt of an inspection report listing unsafe conditions, the labor commissioner will send to the owner and the special inspector, if any, an abatement order. A copy of the inspection report shall be attached to the abatement order. Unless a special inspector conducted the inspection, the order may specify a period that ends no more than 45 days after the inspection during which the owner may submit written evidence that the unsafe conditions have been corrected. The abatement order shall:

(1) Identify the equipment.

(2) Demand that the unsafe conditions be corrected within the period set forth in the inspection report.

(3) Set forth the consequences of failure to comply.

b. After the period specified on the inspection report has passed, the labor commissioner may cause a state inspector to verify correction of all unsafe conditions. If reinspection reveals no significant progress toward correcting the unsafe conditions, or the remaining unsafe conditions create significant safety concerns, the labor commissioner may serve a notice of intent to suspend, deny or revoke the operating permit.

c. The labor commissioner may issue an operating permit after receipt of the appropriate fee and verification that each unsafe condition identified in the inspection report has been corrected.

d. If written proof of correction was requested in the abatement order, but adequate proof was not received by the deadline set forth in the abatement order, the labor commissioner may send a second abatement order or cause a state inspector to inspect the conveyance. If the labor commissioner elects to send a second abatement order, it shall notify the owner that, if written proof of abatement is not received within 20 days, a state inspector may be sent to the site. Copies of the abatement order and the inspection report shall be attached to the second abatement order.

e. If a special inspector conducted the inspection, more than 45 days have passed since the deadline for correction of hazards, and an inspection report indicating the hazards are corrected has not been filed, the labor commissioner may contact the special inspector, send a second abatement order to the owner, or send a state inspector to inspect the conveyance. Copies of the abatement order and the inspection report shall be attached to a second abatement order.

f. If an inspection as described in paragraph 71.11(7)*"d"* or *"e"* reveals no significant progress toward correcting the unsafe conditions, and the remaining unsafe conditions create no significant safety concerns, the labor commissioner may extend the time for abatement of the unsafe conditions an additional 10 days or may serve a notice of intent to suspend, deny or revoke the operating permit. The labor commissioner may also post a notice prohibiting use of the conveyance pending abatement of the unsafe conditions listed in the inspection report.

g. Procedures for appeal of a notice of intent to suspend, deny or revoke an operating permit are set forth in 875—Chapter 69.

71.11(8) *Imminent danger.* If the labor commissioner determines that continued operation of a conveyance pending correction of unsafe conditions creates an imminent danger, the labor commissioner shall post notice on the conveyance that it is not to be used pending repairs. Use of a conveyance contrary to posted notice by the labor commissioner may result in additional legal proceedings pursuant to Iowa Code section 89A.10(3) or 89A.18. The conveyance may be returned to service only after the imminent danger has been corrected and the conveyance has passed a comprehensive inspection.

71.11(9) *Interference prohibited.* No person shall interfere with, delay or impede an inspector employed by the state during an inspection.

71.11(10) *Escalator inspections.* The owner shall arrange for an escalator mechanic to be on site to assist with the inspection. The inspector shall work with the owner to arrange an inspection time.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09; **ARC 9221B**, IAB 11/17/10, effective 12/22/10; **ARC 0168C**, IAB 6/13/12, effective 7/18/12; **ARC 0685C**, IAB 4/17/13, effective 5/22/13; **ARC 1971C**, IAB 4/29/15, effective 6/3/15; **ARC 2607C**, IAB 7/6/16, effective 8/10/16; **ARC 3742C**, IAB 4/11/18, effective 5/16/18; **ARC 3856C**, IAB 6/20/18, effective 8/1/18]

875—71.12(89A,252J,261,272D) Special inspector commissions.

71.12(1) *Definition.* As used in this rule, "certificate of noncompliance" means:

a. A certificate of noncompliance issued by the child support recovery unit, department of human services, pursuant to Iowa Code chapter 252J;

b. A certificate of noncompliance issued by the college student aid commission pursuant to Iowa Code chapter 261; or

c. A certificate of noncompliance issued by the centralized collection unit of the department of revenue pursuant to Iowa Code chapter 272D.

71.12(2) *Qualifications.*

a. Each applicant must possess a high school diploma or general equivalency degree.

b. Each applicant shall have at least three years of full-time work experience in the construction, installation, repair or inspection of conveyances.

c. Each applicant shall be a CEI.

d. Each applicant shall satisfactorily pass a division of labor services examination on Iowa procedures, Iowa policies, and all safety standards adopted by reference.

e. Each applicant shall submit proof of insurance coverage insuring the applicant against liability for injury or death for any act or omission on the part of the applicant. The insurance policy shall be in an amount of not less than $1,000,000 for bodily injury to or death of one person in any one accident, and in an amount of not less than $5,000,000 for bodily injury to or death of two or more persons in any one accident, and in an amount of not less than $100,000 for damage to or destruction of property in any one accident. The insurance coverage of the special inspector's employer shall be considered to comply with this requirement if the coverage provides equivalent coverage for each special inspector.

71.12(3) *Application.* An applicant for a commission shall complete, sign, and submit to the division the form provided by the division with the required fee. The applicant shall include with the application proof that the applicant is a CEI.

71.12(4) *Expiration.* The commission expires when the commission is suspended or revoked by the labor commissioner or one year from issuance, whichever occurs earlier.

71.12(5) *Changes.* The special inspector shall notify the division at the time any of the information on the form or attachments changes.

71.12(6) *Denials.* The labor commissioner may refuse to issue or renew a special inspector's commission for failure of the applicant to complete an application package, if the applicant is not a CEI, or for any reason listed in subrules 71.12(8) to 71.12(10).

71.12(7) *Investigations.* The labor commissioner may investigate for any reasonable cause related to special inspectors or special inspector applicants. The labor commissioner may conduct interviews and utilize other reasonable investigatory techniques. Investigations may be conducted without prior notice at the times and in the places the labor commissioner directs. The labor commissioner may notify the organization that certified the special inspector as a CEI of the findings of an investigation.

71.12(8) *Reasons for probation.* The labor commissioner may issue a notice of commission probation when an investigation reasonably reveals that the special inspector filed inaccurate reports.

71.12(9) *Reasons for suspension.* The labor commissioner may issue a notice of commission suspension when an investigation reasonably reveals any of the following:

a. The special inspector failed to submit and report inspections on a timely basis;

b. The special inspector abused the special inspector's authority;

c. The special inspector misrepresented self as a state inspector or a state employee;

d. The special inspector used commission authority for inappropriate personal gain;

e. The special inspector failed to follow the division's rules for inspection of object repairs, alterations, construction, installation, or in-service inspection;

f. The special inspector committed numerous violations as described in subrule 71.12(8);

g. The special inspector used fraud or deception to obtain or retain, or to attempt to obtain or retain, a special inspector commission whether for one's self or another;

h. The special inspector is no longer a CEI;

i. The division received a certificate of noncompliance; or

j. The special inspector failed to take appropriate disciplinary actions against a subordinate special inspector who has committed repeated acts or omissions listed in paragraphs 71.12(9)*"a"* to *"h."*

71.12(10) *Reasons for revocation.* The labor commissioner may issue a notice of revocation of a special inspector's commission when an investigation reveals any of the following:

a. The special inspector filed a misleading, false or fraudulent report;

b. The special inspector failed to perform a required inspection;

c. The special inspector failed to file a report or filed a report which was not in accordance with the provisions of applicable standards;

d. The special inspector committed repeated violations as described in subrule 71.12(9);

e. The special inspector used fraud or deception to obtain or retain, or to attempt to obtain or retain, a special inspector commission whether for one's self or another;

f. The special inspector instructed, ordered, or otherwise encouraged a subordinate special inspector to perform the acts or omissions listed in paragraphs 71.12(10)*"a"* to *"e"*;

g. The special inspector is no longer a CEI; or

h. The division received a certificate of noncompliance.

71.12(11) *Procedures.* The following procedures shall apply except in the event of revocation or suspension due to receipt of a certificate of noncompliance. In instances involving receipt of a certificate of noncompliance, the applicable procedures of Iowa Code chapter 252J, 261, or 272D shall apply.

a. Notice of actions. The labor commissioner shall serve a notice on the special inspector by certified mail to an address listed on the commission application form or by other service as permitted by Iowa Code chapter 17A.

b. Contested cases. The special inspector shall have 20 days to file a written notice of contest with the labor commissioner. If the special inspector does not file a written contest within 20 days of receipt of the notice, the action stated in the notice shall automatically be effective.

c. Hearing procedures. The hearing procedures in 875—Chapter 1 shall govern.

d. Emergency suspension. Pursuant to Iowa Code section 17A.18A, if the labor commissioner finds that the public health, safety or welfare imperatively requires emergency action because a special inspector failed to comply with applicable laws or rules, the special inspector's commission may be summarily suspended.

e. Probation period. A special inspector may be placed on probation for a period not to exceed one year for each incident causing probation.

f. Suspension period. A special inspector's commission may be suspended up to five years for each incident causing a suspension.

g. Revocation period. A special inspector's commission that has been revoked shall not be reinstated for five years.

h. Concurrent actions. Multiple actions may proceed at the same time against any special inspector.

i. Revoked or suspended commissions. Within five business days of final agency action revoking or suspending a special inspector commission, the special inspector shall surrender the special inspector's commission card to the labor commissioner. The labor commissioner may notify the special inspector's employer and the organization that certified the special inspector as a CEI of a revocation or suspension.

[**ARC 7841B**, IAB 6/17/09, effective 7/22/09]

875—71.13(89A) State employees. Rescinded **ARC 1971C**, IAB 4/29/15, effective 6/3/15.

875—71.14(89A) Safety tests. Only safety test reports submitted on approved forms from elevator mechanics who are employed by authorized companies shall be considered to meet the requirements of this rule. The alternative test methods set forth at ASME A17.1, Rule 8.6.11.10, shall not be allowed as a substitute for a full-load safety test.

71.14(1) *When safety tests will be performed.*

a. Safety tests shall be performed on new and altered installations before they are placed in service.

b. Category 1 safety tests of wind turbine tower elevators shall be conducted after two years of operation, and category 5 safety tests of wind turbine tower elevators shall be performed after ten years of operation. Safety tests shall be made on all other conveyances pursuant to the schedules and procedures set forth in:

(1) The maintenance control plan for wind tower lifts exempted from ASME A17.1 by rule 875—72.12(89A);

(2) The CCD for conveyances covered by ASME A17.7-2007/CSA B44-07;

(3) The columns pertaining to "periodic tests" in Table N-1 in the edition of ASME A17.1 currently adopted for new conveyances at rule 875—72.1(89A);

(4) ASME A18.1(2003), Part 10; or

(5) ANSI A10.4-2007, Section 26.4.

71.14(2) *How safety tests will be reported.* Within 30 days after completion of a safety test, the elevator mechanic shall file with the labor commissioner a report on an approved form and shall provide a copy of the form to the owner and to the witness, if applicable.

71.14(3) *How safety tests will be recorded.* The elevator mechanic shall attach a tag showing the date of the test, the elevator mechanic's name, and the type of test performed.

a. On electric traction elevators, the elevator mechanic shall attach the tag to the safety-releasing carrier.

b. On hydraulic elevators, the elevator mechanic shall attach the tag to the disconnecting switch or the controller.

c. On wheelchair lifts, the elevator mechanic shall attach the tag to the disconnecting switch.

d. On other conveyances covered by these rules, the commissioner's designee witnessing the acceptance safety test shall indicate the proper location of the tag. Subsequent test tags shall be attached in the same location.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09; **ARC 9221B**, IAB 11/17/10, effective 12/22/10; **ARC 0168C**, IAB 6/13/12, effective 7/18/12; **ARC 1766C**, IAB 12/10/14, effective 1/14/15; **ARC 3742C**, IAB 4/11/18, effective 5/16/18]

875—71.15(89A) Authorized companies.

71.15(1) Each year, authorized companies shall train their elevator mechanics who perform safety tests on safety test procedures.

71.15(2) For each conveyance owned by an authorized company, the owner shall obtain the services of a CEI who is not employed by the authorized company or an inspector employed by the state to witness the safety test.

71.15(3) To become authorized to perform safety tests, a company shall submit a copy of its procedures for performing safety tests. The labor commissioner shall review the procedures for adequacy and shall request modifications to the procedures or grant or deny the authorization.

71.15(4) Every five years or within six months after the board adopts a new edition of ASME, whichever is earlier, authorized companies shall submit revised safety test procedures for renewal of authorization. The labor commissioner shall review the procedures for adequacy and shall request modifications to the procedures or grant or deny the authorization.

71.15(5) Investigations. Investigations shall take place at the times and in the places the labor commissioner directs. The labor commissioner may investigate for any reasonable cause. The labor commissioner may conduct interviews and utilize other reasonable investigatory techniques. Investigations may be conducted without prior notice.

71.15(6) Suspension. If the labor commissioner determines that a falsified safety test report was submitted by an elevator mechanic, the labor commissioner shall suspend the authorization of the elevator mechanic's employer for six months. During the suspension, all safety tests performed by any employee of the authorized company shall be witnessed by a state inspector or a CEI who is not employed by the suspended authorized company.

71.15(7) Suspension procedures.

a. The labor commissioner shall notify an authorized company of its suspension by certified mail or by other service as permitted by Iowa Code chapter 17A.

b. The authorized company shall have 20 days to file a written notice of contest with the labor commissioner. If the authorized company does not file a written notice of contest in a timely manner, the suspension shall automatically be effective. If the authorized company does file a written notice of contest in a timely manner, the hearing procedures in 875—Chapter 1 shall govern.

c. If the labor commissioner finds, pursuant to Iowa Code section 17A.18A, that public health, safety or welfare imperatively requires emergency action, the authorization may be summarily suspended.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09]

875—71.16(89A) Fees. Except as noted in this rule, all fees are nonrefundable and due in advance.

71.16(1) *Operating permits.* The annual operating permit fee shall be $75 per conveyance.

71.16(2) *Periodic inspections.* Fees shall be remitted to the division of labor services within 30 days of the date of inspection. The fees for periodic inspections shall be as follows:

a. Construction elevator: $200.
b. Wind tower lift: $225.
c. Hand-powered elevator: $90.
d. Television tower elevator: $500.
e. Handicapped restricted use elevator: $100.
f. Other hydraulic elevator: $100.
g. Other traction elevator: $150.
h. Escalator: $150.
i. Dumbwaiter: $90.
j. Wheelchair lift: $90.
k. CPH.
(1) Annual: $500.
(2) Quarterly: $200.
l. Moving walk: $150.

71.16(3) *Installation permits.* The fees in this subrule cover the initial print review, installation permit, initial inspection and first-year operating permit. Each print revision submitted to the division shall be subject to an additional fee of $100. The fees for new installations shall be as follows:

a. Wind tower lift: $500.
b. Material lift elevators: $500.
c. Other hydraulic elevators: $750.
d. Other traction elevators: $1000.
e. Escalator: $1000.
f. Dumbwaiter: $500.
g. Wheelchair lift: $500.
h. CPH: $500.
i. Moving walk: $500.

71.16(4) *Alteration permits.*

a. The fee for any elevator alteration permit shall be $500 and shall cover the initial print review, alteration permit, and initial inspection.

b. The fee for each CPH extension shall be $150. The total fee required for all planned CPH extensions shall be submitted with the installation permit application pursuant to subrule 71.5(3).

c. The fee for an alteration permit shall be $500 if the only alteration is the addition or replacement of an escalator skirt brush.

d. For all other conveyances, the fees for new installations shall apply to alterations.

71.16(5) *Construction permits.* The construction permit fee shall be $200 per conveyance. This fee includes the fee for initial inspection.

71.16(6) *Controller upgrade permits.* The controller upgrade permit fee shall be $250. This fee includes one inspection.

71.16(7) *Consultative inspections.* Consultative inspections may be performed at the discretion of the labor commissioner for $125 per hour, including travel time, with a minimum charge of $250.

71.16(8) *Special inspector commission.* The special inspector commission fee shall be $60 annually.

71.16(9) *Witness of safety tests.* The fee for division employees to witness safety tests shall be $125 per hour, including travel time, with a minimum charge of $250.

71.16(10) *Permit extensions.* The fee to extend an installation permit, alteration permit, or construction permit shall be $100.

71.16(11) *Inspections outside of normal business hours.* Inspections outside the normal business hours may be performed at the discretion of the labor commissioner. If the owner or contractor requests an inspection outside of normal business hours and the labor commissioner agrees to the schedule, an additional fee will be charged. The additional fee will be calculated at a rate of $200 per hour, including travel time, with a minimum charge of $400.

71.16(12) *Reinspections.* The fees for reinspections are $400 for television tower elevators and CPHs, $200 for wind tower lifts, and $300 for all other conveyances.

71.16(13) *Inspection for temporary removal from service.* The inspection fee for temporary removal from service pursuant to rule 875—71.20(89A) shall be $125 per hour, including travel time, with a minimum charge of $250.

71.16(14) *Fee waiver.*

a. When a state inspector combines in one visit two different types of inspection on a single conveyance, the commissioner may waive the lesser of the fees.

b. The fee for an alteration permit shall be waived by the commissioner if the only alterations covered by the permit application are required by rule 875—72.26(89A) or 875—73.27(89A). The fee waiver set forth in this paragraph does not eliminate the requirement to pay for an acceptance inspection or for an operating permit.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09; **ARC 9221B**, IAB 11/17/10, effective 12/22/10; **ARC 0318C**, IAB 9/5/12, effective 10/10/12; **ARC 0685C**, IAB 4/17/13, effective 5/22/13; **ARC 1158C**, IAB 10/30/13, effective 12/4/13; **ARC 1972C**, IAB 4/29/15, effective 6/3/15; **ARC 1971C**, IAB 4/29/15, effective 6/3/15; **ARC 2603C**, IAB 7/6/16, effective 8/10/16]

875—71.17(89A) Publications available for review. Standards, codes, and publications adopted by reference in these rules are available for review in the office of the Division of Labor Services, 1000 E. Grand Avenue, Des Moines, Iowa 50319.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09]

875—71.18(89A) Other regulations affecting elevators. Regulations concerning accessibility of buildings and conveyances available to the public are found at 661—Chapter 302. Regulations governing the safety and health of employees who work in and around elevators are found at 875—Chapters 2 to 26. Iowa Code chapter 91C and 875—Chapter 150 apply to companies that alter and install conveyances. No rule in 875—Chapters 71 to 73 shall be interpreted as creating an exemption, waiver, or variance from any otherwise applicable regulation or statute.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09]

875—71.19(89A) Accidents and injuries.

71.19(1) This rule applies to a conveyance in the event one of the following occurs:

a. A personal injury accident that requires the service of a physician;

b. A personal injury accident that causes disability exceeding one day; or

c. Damage that will require more than one hour of mechanic's time (excluding travel) to repair.

71.19(2) The owner shall promptly notify the commissioner if one of the events listed in subrule 71.19(1) occurs. Notification shall be in writing and shall include the state identification number, owner, and description of accident.

71.19(3) The removal of any part of the damaged conveyance or operating mechanism from the premises is forbidden until permission is granted by the commissioner.

71.19(4) When an accident or injury involves the failure or destruction of any part of the conveyance or its operating mechanism, the use of the conveyance is forbidden until it has been inspected and approved by the commissioner.
[**ARC 7840B**, IAB 6/17/09, effective 7/22/09; **ARC 3856C**, IAB 6/20/18, effective 8/1/18]

875—71.20(89A) Temporary removal from service. The requirements for an annual inspection, annual inspection fee, safety test, operating permit, and operating permit fee shall be temporarily suspended for up to three years for an elevator in an unoccupied building if the requirements of this rule are met.

71.20(1) All elevator doors in unoccupied buildings shall be closed and locked. Hydraulic elevators shall be parked at the bottom of the hoistway. Traction elevators shall be parked at the top of the hoistway.

71.20(2) Upon request by the owner of an elevator in an unoccupied building, the labor commissioner shall send an inspector who is a state employee to confirm that the building is unoccupied and that the car and doors of the elevator have been properly secured. If the conditions set forth in subrule 71.20(1) are met, the inspector shall apply to the elevator a seal and a red tag marked with the words "Do Not Operate."

71.20(3) One year after the inspection, the owner must file with the labor commissioner written confirmation that the status of the elevator and building have not changed, and the owner must file again two years after the inspection. Failure to comply with this requirement shall result in termination of the temporary suspension of the requirements for safety tests, inspections, and operating permits.

71.20(4) Prior to returning the elevator to service, and upon request of the owner, the labor commissioner may allow the elevator to be operated for 30 days for the sole purpose of performing safety tests and maintenance.

71.20(5) The owner must notify the labor commissioner at least two weeks before placing an elevator back into service and must arrange for an inspector who is a state employee to witness a safety test.

71.20(6) If at the end of three years the building is still unoccupied, suspension of the requirements for safety tests, inspections, and operating permits shall end without possibility of renewal.
[**ARC 0318C**, IAB 9/5/12, effective 10/10/12]

These rules are intended to implement Iowa Code chapters 89A, 252J, 261 and 272D.

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CHAPTER 72
CONVEYANCES INSTALLED ON OR AFTER JANUARY 1, 1975

[Prior to 9/24/86, Labor, Bureau of [530]]
[Prior to 10/21/98, see 347—Ch 72]

875—72.1(89A) Purpose and scope. This chapter contains safety standards covering the design, construction, installation, operation, inspection, testing, maintenance, alteration and repair of conveyances installed on or after January 1, 1975. The rules of this chapter also apply to previously dormant conveyances that are being reactivated, and to reinstalled or moved conveyances. As used in this rule, the word "installation" refers to the date on which a conveyance contractor enters into a contractual agreement pertaining to a conveyance.

72.1(1) For installations between January 1, 1975, and December 31, 1982, ANSI A17.1 shall mean ANSI A17.1 (1971).

72.1(2) For installations between January 1, 1983, and December 31, 1992:

a. ANSI A17.1 shall mean ANSI A17.1 (1981); and

b. ANSI A117.1 shall mean ANSI A117.1 (1980).

72.1(3) For installations between January 1, 1993, and December 31, 2000:

a. ASME A17.1 shall mean ASME A17.1 (1990) and in addition shall mean the following:

(1) ASME A17.1b (1992), Rule 110.11h, for electric elevators installed between July 1, 1993, and December 31, 2000, and

(2) ASME A17.1b (1992), Rule 110.11h that is referenced by Rule 300.11, for hydraulic elevators installed between July 1, 1993, and December 31, 2000.

b. ANSI/NFPA 70 shall mean ANSI/NFPA 70 (1990); and

c. ANSI A117.1 shall mean ANSI A117.1 (1980).

72.1(4) For installations between January 1, 2001, and December 31, 2003:

a. ASME A17.1 shall mean ASME A17.1 (1996 through the 1999 addenda);

b. ASME A18.1 shall mean ASME A18.1 (1999), except Chapters 4, 5, 6, and 7;

c. ANSI A117.1 shall mean ANSI A117.1 (1998); and

d. ANSI/NFPA 70 shall mean ANSI/NFPA 70 (1999).

72.1(5) For installations between January 1, 2004, and April 4, 2006:

a. ASME A17.1 shall mean ASME A17.1 (2000 through the 2003 addenda);

b. ASME A18.1 shall mean ASME A18.1 (1999 through the 2001 addenda), except Chapters 4, 5, 6, and 7;

c. ANSI A117.1 shall mean ANSI A117.1 (1998); and

d. ANSI/NFPA 70 shall mean ANSI/NFPA 70 (2002).

72.1(6) For installations between April 5, 2006, and July 22, 2008:

a. ASME A17.1 shall mean ASME A17.1-2004, A17.1a-2005 and A17.1S-2005;

b. ASME A18.1 shall mean ASME A18.1 (2003), except Chapters 4, 5, 6, and 7;

c. ANSI A117.1 shall mean ANSI A117.1 (2003), except for Rule 407.4.6.2.2; and

d. ANSI/NFPA 70 shall mean ANSI/NFPA 70 (2005).

72.1(7) For installations between July 23, 2008, and July 18, 2012:

a. ASME A17.1 shall mean ASME A17.1-2007/CSA B44-07;

b. ASME A17.7 shall mean ASME A17.7-2007/CSA B44-07;

c. ASME A18.1 shall mean ASME A18.1 (2003), except Chapters 4, 5, 6, and 7;

d. ANSI A117.1 shall mean ANSI A117.1 (2003), except for Rule 407.4.6.2.2; and

e. ANSI/NFPA 70 shall mean ANSI/NFPA 70 (2005).

72.1(8) For installations between July 19, 2012, and January 30, 2014:

a. ASME A17.1 shall mean ASME A17.1-2010/CSA B44-10, except for Rule 2.27.1.1.6;

b. ASME A17.7 shall mean ASME A17.7-2007/CSA B44-07;

c. ASME A18.1 shall mean ASME A18.1 (2003), except Chapters 4, 5, 6, and 7;

d. ANSI A117.1 shall mean ANSI A117.1 (2003), except for Rule 407.4.6.2.2; and

e. ANSI/NFPA 70 shall mean ANSI/NFPA 70 (2008).

72.1(9) For installations between January 31, 2014, and January 14, 2015:
a. ASME A17.1 shall mean ASME A17.1-2010/CSA B44-10, except for Rule 2.27.1.1.6;
b. ASME A17.7 shall mean ASME A17.7-2007/CSA B44-07;
c. ASME A18.1 shall mean ASME A18.1 (2011), except Chapters 4, 5, 6, and 7;
d. ANSI A117.1 shall mean ANSI A117.1 (2003), except for Rule 407.4.6.2.2; and
e. ANSI/NFPA 70 shall mean ANSI/NFPA 70 (2008).
72.1(10) For installations between January 14, 2015, and May 16, 2018:
a. ASME A17.1 shall mean ASME A17.1-2013/CSA B44-13;
b. ASME A17.7 shall mean ASME A17.7-2007/CSA B44-07;
c. ASME A18.1 shall mean ASME A18.1 (2011), except Chapters 4, 5, 6, and 7;
d. ANSI A117.1 shall mean ANSI A117.1 (2003), except for Rule 407.4.6.2.2; and
e. ANSI/NFPA 70 shall mean ANSI/NFPA 70 (2011).
72.1(11) For installations on or after May 16, 2018:
a. ASME A17.1 shall mean ASME A17.1-2016/CSA B44-16;
b. ASME A17.7 shall mean ASME A17.7-2012/CSA B44.7-12;
c. ASME A17.8 shall mean ASME A17.8-2016/CSA B44.8-16;
d. ASME A18.1 shall mean ASME A18.1 (2014), except Chapters 4, 5, 6, and 7;
e. ANSI A117.1 shall mean ANSI A117.1 (2017), except for requirement 407.4.7.1.2; and
f. ANSI/NFPA 70 shall mean ANSI/NFPA 70 (2017).
[**ARC 7840B**, IAB 6/17/09, effective 7/22/09; **ARC 8759B**, IAB 5/19/10, effective 6/23/10; **ARC 0168C**, IAB 6/13/12, effective 7/18/12; **ARC 1232C**, IAB 12/11/13, effective 1/31/14; **ARC 1766C**, IAB 12/10/14, effective 1/14/15; **ARC 1971C**, IAB 4/29/15, effective 6/3/15; **ARC 3742C**, IAB 4/11/18, effective 5/16/18; **ARC 3856C**, IAB 6/20/18, effective 8/1/18]

875—72.2(89A) Definitions. The definitions contained in ASME A17.1, ASME A18.1, ANSI A117.1, and any other standard adopted herein by reference shall be applicable as used in this chapter to the extent that the definitions do not conflict with the definitions contained in Iowa Code chapter 89A and these rules. However, the definition of "building code" in ASME A17.1 is modified to exclude the Building Construction and Safety Code (NFPA 5000) and the National Building Code of Canada (NBCC) for any installation after March 1, 2008.
[**ARC 7840B**, IAB 6/17/09, effective 7/22/09]

875—72.3(89A) Accommodating the physically disabled. All passenger elevators installed between January 1, 1975, and December 31, 1982, which are available and intended for public use shall be usable by the physically disabled. All passenger elevators shall have control buttons with identifying features for the benefit of the blind and shall allow for wheelchair traffic. All passenger elevators and wheelchair lifts installed on or after January 1, 1983, which are accessible to the general public shall comply with Accessible and Usable Buildings and Facilities ANSI A117.1, sections 407 and 408.

875—72.4(89A) Electric elevators. The provisions contained in ASME A17.1, part 2, are adopted by reference.

875—72.5(89A) Hydraulic elevators. The provisions contained in ASME A17.1, part 3, are adopted by reference.

875—72.6(89A) Power sidewalk elevators. The provisions contained in ASME A17.1, section 5.5, are adopted by reference.

875—72.7(89A) Performance-based safety code. Conveyances may comply with ASME A17.7, in whole or in part, as an alternative to ASME A17.1.

875—72.8(89A) Hand and power dumbwaiters. The provisions contained in ASME A17.1, sections 7.1, 7.2, 7.3, and 7.8, are adopted by reference.

875—72.9(89A) Escalators and moving walks. The provisions contained in ASME A17.1, part 6, are adopted by reference, except for those portions that allow an operating or safety device to reset automatically.
[**ARC 1766C**, IAB 12/10/14, effective 1/14/15]

875—72.10(89A) General requirements.

72.10(1) The provisions contained in ASME A17.1, Part 8, are adopted by reference unless specifically excluded herein.

72.10(2) Except as noted in this rule, the American Society of Mechanical Engineers Safety Code for Existing Elevators and Escalators, A17.3 (2011), is adopted by reference with an enforcement date of May 1, 2020.

a. If a code provision that is more restrictive than A17.3 (2011) applied to a conveyance when the conveyance was installed, the more restrictive provision shall remain in effect.

b. A17.3 (2011) Part X applies to handicapped restricted use elevators without regard to the scope provisions set forth in A17.3 (2011) Part X.

c. Provisions of A17.3 (2011) that require installation of a new controller to implement Phase 1 and Phase 2 fire service or car top operation are not adopted by reference and shall not be enforced in Iowa.

d. A17.3 (2011), Rule 2.3.2, is intended to prevent the accumulation of sewer gas in an elevator pit and shall not be interpreted to require the addition of a drain pipe in an existing pit. An air gap in an existing drain pipe shall be considered adequate compliance.

e. An elevator that was legally installed with guide rails made of materials other than steel shall not be required to replace the guide rails due to the adoption of A17.3 (2011).
[**ARC 1891C**, IAB 3/4/15, effective 4/8/15]

875—72.11(89A) Acceptance and periodic tests and inspections of elevators, dumbwaiters, escalators and moving walks. Rescinded IAB 6/17/09, effective 7/22/09.

875—72.12(89A) Wind tower lifts. Wind tower lifts authorized by this rule shall not be installed in grain elevators, high-rise buildings, water towers, television towers or any facility other than a wind tower built for the production of electricity. This rule applies to all wind tower lifts, whether installed before or after May 28, 2008; however, this exception shall not apply to a wind tower lift if the contract for its installation is executed after an AECO is accredited.

72.12(1) Wind tower lifts that meet the requirements of subrules 72.12(2) through 72.12(10) are exempt from the requirements of ASME A17.1. This temporary exemption shall terminate for a wind tower lift upon the occurrence of at least one of the following events:

a. Three weeks have passed since the accreditation of at least one AECO, and the manufacturer of the wind tower lift has not filed with the labor commissioner an affidavit attesting that a request for Certificate of Conformance as described by ASME A17.7 (2007) was submitted to an AECO.

b. The AECO has reviewed a request pursuant to ASME A17.7 and refused to issue a Certificate of Conformance for the model or series of lifts.

c. The AECO has determined that modifications to the wind tower lift are necessary, and the modifications have not been made with reasonable diligence.

d. The AECO has determined that modifications to the wind tower lift are necessary, and the labor commissioner determines the wind tower lift is not safe to operate prior to completion of the modifications.

e. The AECO has reviewed an application pursuant to ASME A17.7 and issued a Certificate of Conformance for the model or series of lifts.

72.12(2) A wind tower lift placed in operation on or before May 28, 2008, shall be registered by the owner with the labor commissioner no later than July 1, 2008, and shall pass an installation inspection by inspectors employed by the labor commissioner according to the schedule set by the labor commissioner. The wind tower lift shall receive a periodic inspection by the labor commissioner's inspectors annually thereafter.

72.12(3) The owner of a wind tower lift installed after May 28, 2008, shall register the wind tower lift with the labor commissioner prior to its installation. A wind tower lift installed after May 28, 2008, shall pass an installation inspection by the labor commissioner's inspectors prior to its being placed into operation. The wind tower lift shall receive a periodic inspection by the labor commissioner's inspectors annually thereafter.

72.12(4) Registration pursuant to this rule requires submission of the following information to the labor commissioner:

a. The unique identifier of the wind tower.

b. The name of the wind tower owner and contact information for the owner's representative.

c. The name of the wind tower lift manufacturer and contact information for the manufacturer's representative.

d. The location of the wind farm.

e. Three copies of the prints and design documents that are certified by a professional engineer duly licensed in the state of Iowa and that bear the professional engineer's P.E. stamp for the lifts.

f. The manufacturer's complete test procedures, inspection checklists, operating manual, service manual, and related documents as determined necessary by the labor commissioner.

72.12(5) The owner shall notify the labor commissioner within 30 days of any change in the information provided pursuant to 72.12(4)*"b"* and *"c."*

72.12(6) This subrule establishes reporting requirements in addition to the requirements of rule 875—71.3(89A). The manufacturer of a lift must notify the labor commissioner in writing within one week if one of its wind tower lifts anywhere in the world is involved in a personal injury accident requiring the service of a physician, a personal injury accident causing disability exceeding one day or death, or an incident causing property damage exceeding $2,000. The notification shall specifically identify the model number, serial number, and owner of the lift, and a description of the incident or accident. The labor commissioner shall determine and require necessary inspections, tests, changes or enhancements to prevent a similar incident or accident in this state.

72.12(7) Wind tower lifts must comply with 29 CFR 1910.

72.12(8) The manufacturer shall notify the labor commissioner within seven days of notification to the manufacturer that an AECO has:

a. Issued a Certificate of Conformance for the model or series of wind tower lifts,

b. Refused to issue a Certificate of Conformance for the model or series of wind tower lifts, or

c. Determined that modifications to the wind tower lifts are necessary.

72.12(9) Wind tower lifts shall pass an inspection covering the following criteria:

a. Ascending speed, descending speed, and emergency descending speed shall not exceed the manufacturer's recommendations.

b. Stop switch, interior lighting, cage entry door, door contact, operating controls and remote operating controls shall operate according to manufacturer's recommendations.

c. Interior floor and cage framework shall appear to be structurally sound.

d. Enclosure signage recommended by the manufacturer shall be in place.

e. Manufacturer's data plate shall be visible.

f. Hoisting mechanism shall appear to be structurally sound and intact from inside and outside the car.

g. Guide shoes shall appear to be structurally sound and undamaged.

h. Suspended power cords and strain relief devices shall reveal no visible damage.

i. Upper and lower normal and final limits shall operate according to the manufacturer's recommendations.

j. Overspeed device shall successfully pass a full-load test.

k. Overload device shall successfully pass an overload test according to the manufacturer's recommendations.

l. Wire rope, safety rope, and guide rope shall show no evidence of wear.

m. Guide rope attachments, suspension attachment beam, beam tower attachments, suspension rope attachment, suspension rope secondary attachment (if present), and guide wire rope attachments shall show no evidence of wear or fatigue.

n. The wind tower lift shall not drift when subjected to a static full load.

o. Maintenance logs, tags, and other necessary documentation shall be available in sufficient detail to establish that maintenance is occurring pursuant to the manufacturer's schedule.

p. Guide rope tension device, safety rope tension device, and suspension rope tension device shall pass a visual test for proper tension.

q. Power cord catch basket shall pass a visual inspection.

r. Safety set distance, overspeed trip speed, overload limit setting, and maximum overload allowed shall not exceed manufacturer's recommendations.

s. A communication device, if installed in the car, shall be operable.

t. Any other items on the manufacturer's recommended inspection checklist shall pass inspection.

72.12(10) The owner or owner's representative shall provide weights as needed to perform necessary tests during inspections.

875—72.13(89A) Alterations, repairs, replacements and maintenance.

72.13(1) *General.* Except as set forth in this rule, all maintenance, repairs, replacements, and alterations shall comply with the edition of ASME A17.1 currently adopted for new conveyances at rule 875—72.1(89A) or ASME A17.7-2007/CSA B44-07, as applicable. Rule 875—71.10(89A) describes alterations which require that the entire conveyance be brought into compliance with the most current codes.

72.13(2) *Exemption for button renumbering.* All maintenance, repairs and alterations to devices covered by ANSI A117.1 shall comply with ANSI A117.1 (2017), except for requirement 407.4.7.1.2.

72.13(3) *Sump pump exemption.* The provisions of ASME A17.1 that require a pit sump or drain shall not apply to an elevator alteration when all of the following criteria are met:

a. No other code or rule requires that the pit be excavated or lowered.

b. The alteration plans do not include the excavation or lowering of the pit floor for any other reason.

c. There is evidence that groundwater has not entered the pit previously.

d. The location and geology of the building indicate a likelihood that groundwater would enter the pit if the foundation or pit floor were breached to install the pit sump or drain.

e. A description of alternative means to maintain the pit in a dry condition is provided to the labor commissioner with the alteration permit application.

f. The labor commissioner approves the alternative means to maintain the pit in a dry condition.

g. The alternative means to maintain the pit in a dry condition are installed or implemented as described in the alteration permit application.

72.13(4) *Pit excavation exemption.* For elevators altered before August 1, 2018, the full length of the platform guard set forth in ASME A17.1, Rule 2.15.9.2(a), shall not be required if all of the following criteria are met:

a. No other code or rule requires that the pit be excavated or lowered.

b. The alteration plans do not include the excavation or lowering of the pit floor for any other reason.

c. A full-length platform guard would strike the pit floor when the elevator is on its fully compressed buffer.

d. The clearance between the bottom of the platform guard and the pit floor is 2.5 centimeters (1 inch) when the elevator is on its fully compressed buffer.

72.13(5) *Sprinkler retrofits and shunt trip breakers.* When a sprinkler is added to a hoistway or machine room, the conveyance shall comply with the following:

a. The installation shall comply with the applicable version of ASME A17.1, Rule 2.8.3.3.

b. The elevator controls shall be arranged to comply with the phase I fire recall provisions of the applicable version of ASME A17.1, Rule 2.27.3.

c. The applicable version of ASME A17.1 shall be determined by reference to rule 875—72.1(89A). For purposes of subrule 72.13(5), the relevant subrule of 875—72.1(89A) shall apply based on the date the sprinkler is installed instead of the date the conveyance was installed.

72.13(6) *Alterations of handicapped restricted use elevators.* A component of a handicapped restricted use elevator being altered shall comply with the portions of ASME A17.1, section 5.3, applicable to the component. The edition of ASME A17.1 adopted by reference in rule 875—72.1(89A) shall be applied.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09; **ARC 1766C**, IAB 12/10/14, effective 1/14/15; **ARC 2396C**, IAB 2/17/16, effective 3/23/16; **ARC 3742C**, IAB 4/11/18, effective 5/16/18; **ARC 3856C**, IAB 6/20/18, effective 8/1/18]

875—72.14(89A) Design data and formulas. Rescinded IAB 11/26/03, effective 1/1/04.

875—72.15(89A) Power-operated special purpose elevators. The provisions contained in ASME A17.1, section 5.7, are adopted by reference.

875—72.16(89A) Inclined and vertical wheelchair lifts. The provisions contained in ASME Safety Standard for Platform Lifts and Stairway Chairlifts A18.1, sections 1, 2, 3, 8, 9, and 10, are adopted by reference for all inclined and vertical wheelchair lifts.

875—72.17(89A) Hand-powered elevators. Hand-powered elevators shall not be installed after January 1, 1983.

875—72.18(89A) Accommodating the physically disabled. Renumbered as 875—72.3(89A), IAB 11/26/03, effective 1/1/04.

875—72.19(89A) Limited-use/limited-application elevators. The provisions contained in ASME A17.1, section 5.2, are adopted by reference.

875—72.20(89A) Rack and pinion, screw-column elevators. The provisions contained in ASME A17.1, sections 4.1 and 4.2, are adopted by reference.

875—72.21(89A) Inclined elevators. The provisions contained in ASME A17.1, section 5.1, are adopted by reference.

875—72.22(89A) Material lift elevators. The provisions contained in ASME A17.1, Sections 7.4 through 7.7 and 7.9 through 7.11, are adopted by reference for material lift elevators installed on or after August 10, 2016.

[**ARC 2603C**, IAB 7/6/16, effective 8/10/16]

875—72.23(89A) Elevators used for construction. The provisions contained in ASME A17.1, section 5.10, are adopted by reference only as they pertain to elevators utilizing permanent equipment in a permanent location.

875—72.24(89A) Construction personnel hoists. The provisions of American National Standards Institute (ANSI) A10.4-2007 are adopted by reference for construction personnel hoists as defined by ANSI A10.4-2007. Notwithstanding the ANSI definition, these conveyances may be used only temporarily during construction.

875—72.25(89A) Alarm bell. An automatic passenger elevator shall be provided with an alarm bell that is activated by a switch marked "ALARM" located in or adjacent to the car operating panel. The alarm bell shall be audible inside the car and outside the hoistway.

[**ARC 0950C**, IAB 8/21/13, effective 9/25/13]

875—72.26(89A) Child entrapment safeguards. This rule applies to a passenger elevator unless it has a car door consisting of a solid panel.

72.26(1) For purposes of this rule, "distance with deflection between the doors or gates" means the distance between the closed car door or gate and the closed hoistway door or gate measured at the greatest perpendicular distance with deflection.

72.26(2) For purposes of this rule, measurements of door or gate deflection shall be made in the manner described by ASME A17.1, section 2.14.4.6.

72.26(3) Door or gate deflection shall not exceed .75 inch.

72.26(4) If the distance with deflection between the doors or gates exceeds 5 inches, a means shall be provided to disable the elevator if a person is in the space between the closed doors or gates.
[**ARC 1972C**, IAB 4/29/15, effective 6/3/15; **ARC 2455C**, IAB 3/16/16, effective 4/20/16]

875—72.27(89A) Handicapped restricted use elevators. All handicapped restricted use elevators must meet ANSI A17.1 (1981), Part V. Additionally, the elevators shall comply with the following limitations:

1. The elevator shall be used only by a maximum of one disabled person and one attendant at a time. Where a disabled person cannot operate the elevator in a manner which will ensure access to all operating controls and safety features, an attendant shall accompany the disabled person.
2. The elevator shall be key-operated and shall not be capable of being called by buttons or switches but may be called by a key operator.
3. Keys to operate the elevator shall be in the control of the disabled person, the attendant or persons in positions of responsibility at the location.
4. A list shall be maintained at the location indicating the persons holding keys for the operation of the elevator.
5. Each landing and the elevator car shall be posted to indicate that the elevator is only for the use of disabled persons.
6. The travel distance of the elevator shall not exceed 50 feet.

[**ARC 1971C**, IAB 4/29/15, effective 6/3/15]

875—72.28(89) Elevators in broadcast towers. This rule applies to special purpose elevators located in broadcast towers.

72.28(1) *Anchorages.* Anchorages compliant with 29 CFR 1926.502(d)(15) shall be attached inside the car and on the car top.

72.28(2) *Emergency stop switch.* An emergency stop switch compliant with ASME A17.1, Sections 2.26.2.8 and 5.7.19, shall be installed on the car top.
[**ARC 2607C**, IAB 7/6/16, effective 8/10/16]

These rules are intended to implement Iowa Code chapter 89A.

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[1] Adopted language of rule 875—72.22(89A) [ARC 6854B, 6/18/08] editorially restored IAC Supplement 2/18/15.

CHAPTER 73
CONVEYANCES INSTALLED PRIOR TO JANUARY 1, 1975

[Prior to 9/24/86, Labor, Bureau of [530]]
[Prior to 10/21/98, see 347—Ch 73]

875—73.1(89A) Scope, definitions, and schedule.

73.1(1) This chapter establishes minimum safety standards for all conveyances installed prior to January 1, 1975, except material lift elevators. Conveyances installed on or after January 1, 1975, shall conform with the requirements set forth in 875—Chapter 72. Material lift elevators installed prior to January 1, 1975, are not subject to regulation pursuant to Iowa Code section 89A.2.

73.1(2) The definitions contained in American National Standard Safety Code for Elevators, Dumbwaiters, Escalators, and Moving Walks, A17.1 (1971), shall be applicable as used in this chapter to the extent that they do not conflict with the definitions contained in Iowa Code chapter 89A or 875—Chapter 71.

73.1(3) Except as noted in this rule, the American Society of Mechanical Engineers Safety Code for Existing Elevators and Escalators, A17.3 (2011), is adopted by reference with an enforcement date of May 1, 2020.

a. If a code provision that is more restrictive than A17.3 (2011) applied to a conveyance when the conveyance was installed, the more restrictive provision shall remain in effect.

b. A17.3 (2011) Part X applies to elevators covered by rule 875—73.21(89A) without regard to the scope provisions set forth in A17.3 (2011) Part X.

c. Provisions of A17.3 (2011) that require installation of a new controller to implement Phase 1 and Phase 2 fire service or car top operation are not adopted by reference and shall not be enforced in Iowa.

d. A17.3 (2011), Rule 2.3.2, is intended to prevent the accumulation of sewer gas in an elevator pit and shall not be interpreted to require the addition of a drain pipe in an existing pit. An air gap in an existing drain pipe shall be considered adequate compliance.

e. The following shall substitute for the final sentence of A17.3 (2011) Rule 2.1.5(b): "Previously installed 60-inch chains are deemed to be in compliance."

f. An elevator that was legally installed with guide rails made of materials other than steel shall not be required to replace the guide rails due to the adoption of A17.3 (2011).

g. Electrical protective devices required by A17.3, requirement 3.10.4, shall cause the electric power to be removed from the elevator driving-machine motor and brake.

h. Control panels that are designed with a door or cover and lock shall be locked when service is not being performed if equipment unrelated to the elevator is in the machine room. Group 1 security as set forth in A17.1, Section 8.1, shall be utilized.

i. A car top emergency exit pursuant to A17.3(2011), requirement 3.4.4.1(a), shall not be required for a hydraulic elevator if the elevator has manual lowering and it is not equipped with a plunger gripper or safety as described in ASME A17.1(2013), requirement 8.6.5.8.

73.1(4) The American Society of Mechanical Engineers Safety Code for Elevators and Escalators, A17.1-2013/CSA B44-13 (2013), Rule 2.14.7.1.4, concerning car top lighting and car top electrical outlets, is adopted by reference with an effective date of May 1, 2020. However, if a car top already has a single outlet, installation of a duplex outlet will not be required.

73.1(5) Rules 875—73.2(89A) to 875—73.6(89A), 875—73.9(89A) to 875—73.17(89A), 875—73.19(89A), 875—73.22(89A), and 875—73.24(89A) and subrules 73.1(2), 73.7(1) to 73.7(9), 73.7(11), 73.18(1), and 73.18(3) to 73.18(7) shall be superseded by corresponding provisions of A17.3 (2011) on May 1, 2020.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09; **ARC 1891C**, IAB 3/4/15, effective 4/8/15; **ARC 3856C**, IAB 6/20/18, effective 8/1/18]

875—73.2(89A) Hoistways.

73.2(1) Each passenger elevator hoistway landing shall be protected with a door or gate. The door or gate shall be of solid construction and shall guard the entire entrance.

73.2(2) All automatic passenger elevators with power doors shall have nonvision panels on hoistway doors.

73.2(3) Each hoistway landing in any elevator hoistway shall be continuously provided with a properly working door or gate.

73.2(4) Where freight elevator hoistway doors or gates are of open or lattice construction, they shall be at least 6 feet high and shall come within 2 inches of the floor when closed. Gates shall be constructed to reject a ball 2 inches in diameter. Doors and gates must be able to withstand 250 pounds of pressure applied in the center of the door or gate without breaking or being forced out of their guides.

73.2(5) Manually operated biparting entrances of elevators which can be operated from the landings shall be provided with pull straps on the inside and outside of the upper panel where the lower edge of the upper panel is more than 6 feet 6 inches above the landing when the panel is in the fully opened position.

73.2(6) All freight elevators having wooden hoistway gates in an area where power loading equipment, such as fork trucks, electric mules, etc. are used shall have an acceptable means to restrain the power equipment from running through such wooden gates.

73.2(7) Each hoistway door or gate shall be provided with interlocks designed to prevent the car from moving unless the doors or gates are closed. Where doors or gates do not lock when closed they shall lock when the elevator is not more than 12 inches away from the floor. Passenger elevator hoistway doors shall be closed and locked before the car leaves the floor.

73.2(8) All hoistway-door interlocks shall function as part of a hoistway-unit system.

73.2(9) Automatic fire doors shall not lock any landing opening in the hoistway enclosure from the hoistway side nor lock any exit leading from any hoistway landing to the outside of the building.

73.2(10) Emergency keys for hoistway doors and service keys shall be kept readily accessible to authorized persons and elevator safety inspectors.

73.2(11) Access means shall be provided at one upper landing to permit access to the top of the car, and at the lowest landing if this landing is the normal point of access to the pit.

73.2(12) Each hoistway door or gate which is counterweighted shall have its weights enclosed in a box-type guide or run in metal guides. The bottom of the guides or boxes shall be so constructed as to retain the counterweight if the counterweight suspension means breaks.

73.2(13) Hoistways containing freight elevators shall be fully enclosed. Enclosures shall be unperforated to a height of 6 feet above each floor or landing and above the treads of adjacent stairways. Unperforated enclosures shall be so supported and braced as to deflect not over 1 inch when subjected to a force of 100 pounds applied horizontally to any point. Open work enclosure may be used above the 6-foot level and shall reject a ball 2 inches in diameter.

73.2(14) Hoistways containing passenger elevators shall be fully enclosed and the enclosure shall be of solid construction to its full height.

73.2(15) All elevators that have automatic leveling, inching or teasing devices and that are configured with landing sills that project into the hoistway shall be equipped with a bevel on the underside of the landing sill or the underside of projections found on the bottom section of vertically opening biparting doors. Bevels shall be constructed of smooth concrete or not less than 16-gauge metal securely fastened to the hoistway entrance. Bevels shall extend the full depth of the leveling zone plus 3 inches.

73.2(16) Every hoistway window opening seven stories or less on an outside wall above a thoroughfare and every such window three stories or less above a roof of the building or of an adjacent building shall be guarded to prevent entrance by fire or emergency rescue persons. Each such window shall be marked "hoistway" in a readily visible manner.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09]

875—73.3(89A) Car enclosure: Passenger.

73.3(1) Each passenger car shall be fully enclosed except on the sides used for entrance and exit. The enclosure shall be of solid construction. Grillwork at the top of the sides shall not be more than 8 inches high. If the car is provided with a solid door and there is no grillwork in the enclosure, adequate means of ventilation shall be provided.

73.3(2) Each passenger car enclosure shall have a top constructed of solid material. The top shall be capable of sustaining a load of 300 pounds on any area of 2 feet on a side and 100 pounds applied at any point. Simultaneous application of these loads is not required.

73.3(3) Passenger car enclosure tops shall have an emergency exit with cover. Opening size shall be as set forth in ANSI A17.1, 1971, Rule 204.1E. Hydraulic elevators provided with a manual lowering valve are not required to provide an emergency exit.

73.3(4) Each passenger car shall have a door or gate at each entrance. Doors or gates shall be of the horizontally sliding type. Doors shall be of solid construction. Gates shall be of the collapsible type. Gates and doors shall conform to ANSI A17.1, 1971, Rule 204.4.

73.3(5) Each passenger car door or gate shall have an electric contact to prevent the car from running with doors or gates open. EXCEPTIONS:

a. By a car-leveling or truck-zoning device.

b. By a combination hoistway access switch and operating device.

c. When a hoistway access switch is operated.

73.3(6) All automatic passenger elevators with power doors shall have reopening devices on the doors, designed to reopen doors in the event the doors should become obstructed.

73.3(7) Car door or gate closing force.

a. Where a car door or gate of an automatic or continuous-pressure operation passenger elevator is closed by power, or is of the automatically released self-closing type, and faces a manually operated or self-closing hoistway door, the closing of the car door or gate shall not be initiated unless the hoistway door is in the closed position. The closing mechanism shall be so designed that the force necessary to prevent closing of a horizontally sliding car door or gate from rest shall be not more than 30 pounds.

b. Paragraph 73.3(7)*"a"* does not apply when both of the following conditions are met:

(1) A car door or gate is closed by power through continuous pressure of a door-closing switch or the car operating device, and

(2) The release of the closing switch or operating device will cause the car door or gate to stop or to stop and reopen.

73.3(8) Each passenger car shall have lighting inside the enclosure of not less than 5 foot-candles. Bulbs and tubes shall be guarded to prevent breakage.

73.3(9) Each passenger elevator shall have a capacity plate prominently displayed in its enclosure. The capacity plate shall list its capacity in pounds.

73.3(10) All passenger elevator car floors shall be maintained so that persons are not exposed to the hazards of tripping or falling.

73.3(11) All automatic passenger elevators shall be provided with an alarm bell capable of being activated from inside the car and audible outside the hoistway. If the elevator is not equipped with a bell, a two-way conversation device to the elevator and a ready accessible point outside the hoistway may be acceptable.

73.3(12) All automatic passenger elevators shall have their door open zones adjusted so that the door shall not open unless the car has stopped within 6 inches of floor level.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09]

875—73.4(89A) Car enclosure: Freight.

73.4(1) Each freight elevator car shall have a solid enclosure at least 66 inches in height. The space between the solid section and the car top shall be enclosed with solid material, perforated material, or latticework. Where used, perforated material or latticework shall reject a ball 1½ inches in diameter. The portion of open-type enclosure which passes the counterweights shall be of solid construction the entire width of the counterweights plus 6 inches on either side. The enclosure top shall be provided with an emergency exit, except for hydraulic elevators with manual lowering valves.

73.4(2) Each freight car enclosure shall have doors or gates at each entrance and shall be not less than 6 feet high. Each door or gate shall be constructed in accordance with ANSI A17.1, 1971, Rule 204.4.

73.4(3) Each car door or gate on a freight elevator shall have electric contacts to prevent the car from running with doors or gates open. EXCEPTIONS:

a. By a car-leveling or truck-zoning device.

b. By a combination hoistway access switch and operating device.

c. When a hoistway access switch is operated.

73.4(4) Each freight elevator car enclosure shall be provided with a top. The top may be of solid or open-work construction and shall be of metal. The openwork shall reject a ball 2 inches in diameter. Car tops shall be constructed to sustain a load of 200 pounds applied at any point on the car top. The top shall not have hinged or folding panels other than the emergency exit cover.

73.4(5) Each freight car enclosure shall have lighting not less than 2½ foot-candles. Bulbs or tubes shall be guarded to prevent breakage.

73.4(6) Each freight car enclosure shall have capacity plate, loading class plates, and a "No Passenger" sign conspicuously posted. Letters shall be not less than ½-inch high.

73.4(7) Freight elevators shall not be loaded to exceed the rated load as stated on their capacity plates.

73.4(8) Each freight elevator car floor shall be maintained so that personnel will not readily slip or trip. The floor shall be maintained so that it will hold its rated load without breaking through at any place in the car.

73.4(9) Freight elevators shall not be permitted to carry passengers other than the operator and persons to load and unload material.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09]

875—73.5(89A) Brakes.

73.5(1) Each electric elevator shall be provided with an electric brake.

73.5(2) Each brake shall be of the friction type applied by a spring or springs or gravity and released electrically. The brake shall be capable of holding the car at rest with its rated load.

875—73.6(89A) Machines.

73.6(1) Friction gearing or clutch mechanisms shall not be used for connecting the drum or sheaves to the main driving mechanism.

73.6(2) Set screw fastenings shall not be used on power elevators in lieu of keys or pins on connections subject to torque or tension.

73.6(3) Portable power-chain or cable hoist machines shall not be used to raise or lower an elevator car.

73.6(4) No belt or chain driven power machine shall be used for any elevator unless the machine is provided with a broken belt or broken chain safety switch of the electrical nonautomatic reset type. EXCEPTION: Hydraulic machines.

875—73.7(89A) Electrical protective devices.

73.7(1) All electric elevators shall have a labeled emergency stop switch. The switch shall be located on or adjacent to the operating panel.

73.7(2) All electric elevators shall have upper and lower final limit switches. Open-type switches shall not be accepted. Drum-type machines shall have final limit switches mounted on the machine and hoistway final limit switches.

73.7(3) All operating devices of car switch operations shall automatically return to the stop position and latch there when released.

73.7(4) Tiller-rope operations shall not be used unless all direction switches on controllers are mechanically operated. Contacts on direction switches shall be broken when the rope is at the centered position.

73.7(5) Except for firefighter service switches, leveling switches, and truck zone switches, no elevator shall be provided with a switch or device which makes more than one door or gate switch inoperative at any one time.

73.7(6) No person at any time shall make any required safety device or electrical protective device inoperative, except where necessary during tests, inspections or maintenance. Such devices shall be restored to their normal operating conditions as soon as all tests, inspections and maintenance have been completed. The conveyance shall not be left unattended while any of these devices are inoperative. To ensure that no jumpers are left behind, a counting system shall be utilized.

73.7(7) Each winding drum machine shall be provided with an electrical switch which shall disconnect power to the hoisting motor and brake when ropes are slackened.

73.7(8) No person shall enter an elevator pit for any reason without disconnecting power to the equipment using the pit stop switch, lockout, tagout procedures, or other appropriate means of de-energization in accordance with 875—Chapters 2 to 26.

73.7(9) Elevators having a polyphase AC power supply shall be provided with means to prevent the starting of the elevator drive motor or door motor if a reversal of phase rotation, or phase failure of the incoming polyphase AC power, will cause the elevator car or elevator door(s) to operate in the wrong direction.

73.7(10) All electrical equipment pertaining to the elevator shall conform to ANSI C1-1975 (NFPA 70-1975).

73.7(11) All electrical wiring in the machine room and hoistway shall be enclosed in metal conduit, flexible conduit or metal raceways.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09; **ARC 1971C**, IAB 4/29/15, effective 6/3/15]

875—73.8(89A) Maintenance, repairs and alterations.

73.8(1) *General.* Except as set forth in this rule, all maintenance, repairs and alterations shall comply with the edition of ASME A17.1, Part 8, currently adopted for new conveyances at rule 875—72.1(89A) or ASME A17.7-2007/CSA B44-07, as applicable. Rule 875—71.10(89A) describes alterations which require that the entire conveyance be brought into compliance with the most current code.

73.8(2) *Exemption for button numbering.* All maintenance, repairs and alterations to devices covered by ANSI A117.1 shall comply with ANSI A117.1 (2017), except for requirement 407.4.7.1.2.

73.8(3) *Sump pump exemption.* The provisions of ASME A17.1 that require a pit sump or drain shall not apply to an elevator alteration when all of the following criteria are met:

a. No other code or rule requires that the pit be excavated or lowered.

b. The alteration plans do not include the excavation or lowering of the pit floor for any other reason.

c. There is evidence that groundwater has not entered the pit previously.

d. The location and geology of the building indicate a likelihood that groundwater would enter the pit if the foundation or pit floor were breached to install the pit sump or drain.

e. A description of alternative means to maintain the pit in a dry condition is provided to the labor commissioner with the alteration permit application.

f. The labor commissioner approves the alternative means to maintain the pit in a dry condition.

g. The alternative means to maintain the pit in a dry condition are installed or implemented as described in the alteration permit application.

73.8(4) *Pit excavation exemption.* The full length of the platform guard set forth in ASME A17.1, Rule 2.15.9.2(a), shall not be required if all of the following criteria are met:

a. No other code or rule requires that the pit be excavated or lowered.

b. The alteration plans do not include the excavation or lowering of the pit floor for any other reason.

c. A full-length platform guard would strike the pit floor when the elevator is on its fully compressed buffer.

d. The clearance between the bottom of the platform guard and the pit floor is 2.5 centimeters (1 inch) when the elevator is on its fully compressed buffer.

73.8(5) *Sprinkler retrofits and shunt trip breakers.* When a sprinkler is added to a hoistway or machine room, the conveyance shall comply with the following:

a. The installation shall comply with the applicable version of ASME A17.1, Rule 2.8.3.3.

b. The elevator controls shall be arranged to comply with the phase I fire recall provisions of the applicable version of ASME A17.1, Rule 2.27.3.

c. The applicable version of ASME A17.1 shall be determined by reference to rule 875—72.1(89A). For purposes of subrule 73.8(5), the relevant subrule of 875—72.1(89A) shall apply based on the date the sprinkler is installed instead of the date the conveyance was installed.

73.8(6) *Safety bulkheads.* Documentation from the manufacturer establishing that a safety bulkhead was installed shall establish compliance with ASME A17.1, Rule 8.6.5.8.

73.8(7) *Alterations of handicapped restricted use elevators.* A component of a handicapped restricted use elevator being altered shall comply with the portions of ASME A17.1, section 5.3, applicable to the component. The edition of ASME A17.1 adopted by reference in rule 875—72.1(89A) shall be applied.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09; **ARC 1766C**, IAB 12/10/14, effective 1/14/15; **ARC 2396C**, IAB 2/17/16, effective 3/23/16; **ARC 3742C**, IAB 4/11/18, effective 5/16/18; **ARC 3856C**, IAB 6/20/18, effective 8/1/18]

875—73.9(89A) Machine rooms.

73.9(1) All means of access to elevator machine rooms shall be of a permanent nature and shall be constructed and maintained in a clear and unobstructed manner.

73.9(2) The elevator machine and control equipment shall be located in a separate room or separated from other equipment by a substantial grill not less than 6 feet high. The grill shall be of a design that will reject a ball 2 inches in diameter. All rooms or enclosures shall have a self-closing and self-locking door.

73.9(3) All elevator machine rooms shall be provided with a floor. The floor shall cover the entire area of the machine room and hoistway.

73.9(4) Machine room floors shall be kept clean and free of grease and oil. Articles or materials not necessary for the maintenance or operation of the elevator shall not be stored therein. Storage of any equipment or materials in elevator machine rooms other than equipment directly related to elevator operation is prohibited.

73.9(5) Lighting in the machine room shall be not less than 10 foot-candles at floor level.

73.9(6) Where there is more than one machine in a room, each machine shall have a different number conspicuously marked on it. The controller, disconnecting means and relay panels for each machine shall be conspicuously numbered to correspond to the machine they control.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09]

875—73.10(89A) Pits.

73.10(1) All pits shall be kept clean and free of equipment or material not relating to the operation of the elevator. EXCEPTION: sump pumps.

73.10(2) Buffers under cars and counterweights shall be permanently fastened to the floor or their supporting beams.

73.10(3) All elevators shall have counterweight guards. Guards shall be of unperforated metal of at least the strength of or braced to the equivalent strength of number 14-gauge sheet steel. Guards shall extend from a point not more than 12 inches above the pit floor to a point not less than 7 feet above the pit floor. Where guards are not feasible, warning chains shall be installed on the bottom of the counterweights and shall extend no less than 5 feet below the counterweight. Chains shall be of a number 10 U.S. gauge wire or of equal size. EXCEPTION: When compensating chains or ropes are used, a counterweight guard is not required.

73.10(4) Buffers shall be installed where elevator pits are not provided with buffers and where the pit depth will permit. Buffers shall comply with ANSI A17.1, 1971, Section 201.

73.10(5) Where the depth of any pit is in excess of 4 feet it shall have a ladder permanently installed. The ladder shall extend not less than 30 inches above the sill of the access door, or hand grips shall be provided to the same height. Ladder shall be of noncombustible material.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09]

875—73.11(89A) Counterweights.

73.11(1) Broken or cracked sections of counterweights shall be replaced.

73.11(2) Counterweight hanger rods, tie rods or both shall firmly support and secure the counterweight sections in place.

73.11(3) Wire ropes extending through counterweights from one stack to another shall be guarded by metal sleeves attached to the wire ropes. Stacks shall not be spaced less than 8 inches apart.

875—73.12(89A) Car platforms and car slings.

73.12(1) All platforms shall be soundly constructed without cracks or breaks in stringers or frames. All floors shall be free of holes.

73.12(2) All car slings shall be soundly constructed and free of cracks or breaks.

73.12(3) Where cable sheaves are used on the crosshead, they shall be firmly attached and free of cracks or breaks.

73.12(4) All elevators shall have data plates attached to the crosshead.

73.12(5) All elevators with automatic leveling, inching or teasing devices shall have a platform guard or an apron. All other elevators shall have warning chains hung within 2 inches of the edge of the platform on the entrance sides. Chains shall be of number 10 U.S. gauge wire or of equal size. Chains shall extend not less than 5 feet below the platform and shall not be spaced more than 4 inches apart.

73.12(6) All car slings shall have guide shoes at the top and bottom of the sling. Shoes that are worn to a degree which affect the safe operation of the car shall be repaired or replaced.

875—73.13(89A) Means of suspension.

73.13(1) Suspension ropes on drum-type machines shall have not less than one turn of the rope on the drum when the car is resting on the fully compressed buffers.

73.13(2) Winding drum machines shall not be used unless they are provided with not less than two hoisting ropes. Each counterweight stack shall be provided with not less than two ropes.

73.13(3) Tiller cables on cable-operated elevators shall be kept free of breaks.

73.13(4) On tiller-cable operations, the cable shall pass through a guiding or stopping device mounted on the car. The cable shall be provided with adjustable stop balls and be provided with means to lock and hold the car at a floor. Stop balls at top and bottom shall be adjusted to automatically stop the car. The tiller cable shall be completely enclosed in the hoistway.

73.13(5) All hoisting or counterweight ropes located outside of the hoistway that are exposed shall be covered with a box-type guard. The guard shall be not less than 6 feet high from floor level.

73.13(6) Roller chains shall not be used as the suspension means for any conveyance except where specifically allowed by an applicable provision of ASME A17.1.

73.13(7) Hoisting ropes for power elevators shall not be less than 3/8 inch in diameter.

73.13(8) Hoisting rope fastening means shall be of the socket and babbitting type. Clamps shall not be used.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09]

875—73.14(89A) Car safeties and speed governors.

73.14(1) Each elevator suspended by ropes shall be provided with mechanically applied car safeties which shall be capable of stopping and sustaining its rated load.

73.14(2) Broken rope or slack rope safeties may be allowed if the car speed is not in excess of 50 FPM.

73.14(3) Elevators which are provided solely with broken rope or slack rope safeties shall not be used for passenger service. EXCEPTION: Handicapped restricted use elevators.

73.14(4) All safeties shall be adjusted so that clearances from the rail shall be in accordance with ANSI A17.1, 1971, Rule 1001.2.

73.14(5) All slack cable safeties shall be provided with an electrical switch which disconnects power to the elevator machine and brake when setting of the safeties occurs.

73.14(6) All safeties operated by a speed governor shall be provided with a speed switch operated by the governor when used with type B or C car safeties on elevators having a rated speed exceeding 150 FPM. A switch shall be provided on the speed governor when used with a counterweight safety for any car speed. The switches required by this subrule shall disconnect power to the elevator driving-machine motor and brake.

73.14(7) Speed governors shall have their means of speed adjustment sealed.

73.14(8) For hoistways not extending to the lowest floor and where space below the hoistway is used for a passageway or is occupied by persons, or if unoccupied but not secured against unauthorized access, the counterweights of the elevator shall be provided with safeties. Safeties shall be tripped by a speed governor if the car speed is in excess of 150 FPM. Speed governors shall be set to trip above the car governor tripping speed but not more than 10 percent greater.

73.14(9) Access to a governor that is located inside a hoistway shall be provided in accordance with ASME A17.1-2007, Rule 2.7.6.3.4.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09; **ARC 8760B**, IAB 5/19/10, effective 6/23/10; **ARC 3856C**, IAB 6/20/18, effective 8/1/18]

875—73.15(89A) Guide rails.

73.15(1) All guide rails and brackets whether of wood or steel shall be firmly and securely anchored or bolted in place. Where T rail is used, all fish-plate bolts shall be tight. This shall comply with ANSI A17.1, 1981, Section 200.

73.15(2) Where guide rails which are worn to such a point that proper clearance of safety jaws cannot be maintained, the worn sections shall be replaced to achieve clearances as specified in ANSI A17.1, 1971, Rule 1001.2.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09]

875—73.16(89A) Existing hydraulic elevators.

73.16(1) Cylinders of hydraulic-elevator machines shall be provided with a means for releasing air or other gas.

73.16(2) Each pump or group of pumps shall be equipped with a relief valve conforming to the following requirements:

a. Type and location. The relief valve shall be located between the pump and the check valve and shall be of such a type and so installed in the bypass connection that the valve cannot be shut off from the hydraulic system.

b. Setting. The relief valve shall be preset to open at a pressure not greater than that necessary to maintain 125 percent of working pressure.

c. Size. The size of the relief valve and bypass shall be sufficient to pass the maximum rated capacity of the pump without raising the pressure more than 20 percent above that at which the valve opens. Two or more relief valves may be used to obtain the required capacity.

d. Sealing. Relief valves having exposed pressure adjustments, if used, shall have their means of adjustment sealed after being set to the correct pressure.

EXCEPTION: No relief valve is required for centrifugal pumps driven by induction motors, provided the shut-off, or maximum pressure which the pump can develop, is not greater than 135 percent of the working pressure at the pump.

73.16(3) Storage and discharge tanks shall be covered and suitably vented to the atmosphere.

73.16(4) Hydraulic elevators shall be governed by the rules contained in Chapter 73 that apply to electric elevators except the following rules which are exempt: 73.5, 73.6(3), 73.7(2), 73.7(4), 73.7(7),, 73.9(9), 73.10(3), 73.11, 73.13, and 73.14.

73.16(5) Rescinded IAB 3/7/01, effective 4/11/01.

875—73.17(89A) Existing sidewalk elevators.

73.17(1) Hoistways shall be permanently enclosed. The enclosures shall conform to ANSI A17.1, 1971, Rule 401.1.

73.17(2) All interior landings shall have a door or gate which shall be provided with an interlock.

73.17(3) Doors opening in sidewalks or other areas exterior to the building shall be of the hinged type. Doors or covers shall be designed to hold a static load of 300 pounds per square foot. Doors shall always be closed unless elevator is at the landing.

73.17(4) Stops shall be provided to prevent the cover in the opening of the sidewalk from opening more than 90 degrees from its closed position.

73.17(5) Covers in sidewalk shall be designed to close when the car descends from the top landing.

73.17(6) Recesses or guides which will securely hold the cover in place on the car stanchions shall be provided on the underside of the cover.

73.17(7) All electrical wiring shall be enclosed in metal conduit, flexible conduit or metal raceways. If hoistway opens in the sidewalk, the wiring shall be weatherproof.

73.17(8) Operating devices and control equipment shall comply with ANSI A17.1, 1971, Rule 402.4.

73.17(9) All electric sidewalk elevators shall have upper and lower final limit switches. Open-type switches shall not be allowed.

73.17(10) Cars shall have enclosures which shall be not less than 6 feet in height provided the stanchions and bow iron are of sufficient height. The enclosure shall be provided with electric contacts to prevent the car from running with doors or gates open.

73.17(11) Cars shall have safeties. Where the speed of the elevator does not exceed 50 FPM, car safeties which operate as a result of breaking or slackening of the hoisting ropes may be used. Such safeties may be of the inertia type or approved type without governors. Governors shall not be required when car speed does not exceed 50 FPM.

73.17(12) Car enclosures and car gates shall not be required for hand-powered sidewalk elevators.

73.17(13) Rescinded IAB 3/7/01, effective 4/11/01.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09]

875—73.18(89A) Existing hand elevators.

73.18(1) Hand-powered elevators shall have hoistway doors. Doors shall be of the self-closing and self-locking type.

73.18(2) A sign reading "Danger—Elevator Hoistway—Keep Closed" shall be mounted on each hoistway door. The letters on the signs shall be legible, shall be at least 2 inches high, and shall contrast with the background color.

73.18(3) All hand-powered elevators shall be provided with safeties or slack cable devices. Safeties do not have to be operated by a speed governor unless the speed is in excess of 50 FPM.

73.18(4) Hand-powered elevators shall have a car enclosure which shall be constructed of metal or sound seasoned wood. The enclosure shall cover all sides which are not used for entrance or exit. The enclosure shall be secured to the car platform or frame in such a manner that it cannot work loose or become displaced in ordinary service.

73.18(5) Each hand-powered elevator shall be provided with a brake which shall be capable of stopping and sustaining the car whether loaded or unloaded.

73.18(6) Hand-powered elevators shall not be converted or changed to electric powered unless the complete conveyance is brought into conformity with 875—Chapter 72.

73.18(7) Rescinded IAB 3/7/01, effective 4/11/01.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09]

875—73.19(89A) Power-operated special purpose elevators.

73.19(1) Elevators complying with the following requirements may be installed in any structure where the elevator is not accessible to the general public, is used exclusively for designated operating and maintenance employees only, and where transportation of one or two persons is required to attend machinery or equipment frequently.

73.19(2) The inside platform area of the car shall not exceed 9 square feet. The rated speed shall not exceed 100 FPM. The rated load shall not exceed 650 pounds.

73.19(3) Hoistways shall be enclosed to their full width, to a height of not less than 7 feet with solid or perforated noncombustible material braced to deflect not more than 1 inch when subjected to a force of 100 pounds applied horizontally at any point. Open work enclosures shall be at least number 13 steel

wire gauge or expanded metal at least number 13 U.S. gauge and shall reject a ball 2 inches in diameter. Where counterweights pass, landing and stairway side shall be of solid construction.

73.19(4) Wiring shall comply with the requirements of the National Electrical Code, ANSI C1-1975 (NFPA 70-1975).

73.19(5) Counterweights shall comply with rule 875—73.11(89A).

73.19(6) Hoistway doors shall comply with subrules 73.2(1), 73.2(7) and 73.2(11).

73.19(7) Cars shall be solidly constructed in accordance with subrules 73.12(1) and 73.12(2).

73.19(8) Car enclosure.

a. Except at the entrance, the car shall be enclosed on all sides and the top. The enclosure at the sides shall be solid or openwork. All openwork shall reject a ball 1 inch in diameter. The enclosure shall be constructed of sufficient strength that it will not deflect more than 1 inch at any one point.

b. There shall be an electric light to illuminate the car or hoistway with the switch placed on or near the operating panel.

c. There shall be no glass used in the elevator car except for the car light.

73.19(9) A car door shall be provided at each car entrance. Door or gate shall guard the complete entrance. The door or gate shall be at least 7 feet high, of metal construction with solid or open construction to reject a ball 1 inch in diameter. A contact switch shall be provided to prevent the operation of the elevator with doors or gates open. The door or gate shall be provided with interlocks.

73.19(10) Guide rails shall comply with rule 875—73.15(89A).

73.19(11) The means and methods of suspension shall comply with subrules 73.13(1), 73.13(5), 73.13(6), 73.13(7), and 73.13(8).

73.19(12) Electrical switches shall comply with subrules 73.7(2) and 73.7(9).

73.19(13) Brakes shall comply with rule 875—73.5(89A).

73.19(14) Emergency signal or communication shall comply with subrule 73.3(11).

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09]

875—73.20(89A) Inclined and vertical wheelchair lifts. All vertical and inclined wheelchair lifts shall conform to ANSI A17.1 (1981), part XX, sections 2000 and 2001.

875—73.21(89A) Handicapped restricted use elevators. All handicapped restricted use elevators must meet ANSI A17.1 (1981), Part V. Additionally, the elevators shall comply with the following limitations:

1. The elevator shall be used only by a maximum of one disabled person and one attendant at a time. Where a disabled individual cannot operate the elevator in a manner which will ensure access to all operating controls and safety features, an attendant shall accompany the disabled individual.
2. The elevator shall be key-operated and shall not be capable of being called by buttons or switches but may be called by a key operator.
3. Keys to operate the elevator shall be in the control of the disabled person, the attendant or persons in positions of responsibility at the location.
4. A list shall be maintained at the location indicating the persons holding keys for the operation of the elevator.
5. Each landing and the elevator car shall be posted to indicate that the elevator is only for the use of disabled persons.
6. The travel distance of the elevator shall not exceed 50 feet.

[**ARC 7840B**, IAB 6/17/09, effective 7/22/09; **ARC 1971C**, IAB 4/29/15, effective 6/3/15]

875—73.22(89A) Escalators.

73.22(1) Each escalator shall be provided with an electrically released mechanically applied brake capable of stopping the up and down traveling escalator with any load up to and including the rated load. The brake shall be located either on the driving machine or on the main drive shaft.

73.22(2) Starting switches shall be of the key-operated type. Starting switches shall be located on or near the escalator.

73.22(3) Emergency stop buttons or other type manually operated switches having red buttons or handles shall be accessibly located at or near the bottom and top landings. The buttons or levers shall be protected to prevent accidental operation.

73.22(4) A broken step-chain device shall be provided on each escalator that will cause interruption of power to the driving machine if a step chain breaks or if excessive sag occurs in either step chain.

73.22(5) Each escalator shall have comb plates at top and bottom landings of the escalator. Comb-plate teeth shall be meshed with and set into slots in the tread surface of the steps so that the points of the teeth are always below the upper surface of the treads.

73.22(6) Each escalator balustrade or moulding on the balustrade shall have a smooth surface. Screwheads shall set flush with the surface or be of the oval head type without any burrs or rough places on their surface.

73.22(7) The clearance on either side of the steps between the step tread and the adjacent skirt panel shall be not more than 3/16 inch.

73.22(8) Step treads shall be illuminated throughout their run. The light intensity shall be not less than 2 foot-candles.

73.22(9) An enclosed fused disconnect switch or circuit breaker arranged to disconnect the power supply to the escalator shall be in each machine room or wherever the controller is located.

73.22(10) A stop switch shall be provided in each machinery space where means of access to the space is provided. The switch when opened shall cause electric power to be removed from the escalator driving-machine motor and brake. The switch shall be of the manually opened and closed type and shall be marked "STOP".

73.22(11) Hand or finger guards shall be provided at the point where the handrail enters the balustrade.

73.22(12) Where the clearance of the upper outside edge of the balustrade and a ceiling or scaffold is less than 12 inches or where the intersection of the outside balustrade and a ceiling or soffit is less than 24 inches from the centerline of the handrail, a solid guard shall be provided in the intersection of the angle of the outside balustrade and the ceiling or soffit. The vertical front edge of the guard shall project a minimum of 14 inches horizontally from the apex of the angle. The escalator side of the vertical face of the guard shall be flush with the face of the wellway. The exposed edge of the guard shall be rounded.

This rule is intended to implement Iowa Code chapter 89A.

875—73.23(89A) Moving walks. Rescinded IAB 6/17/09, effective 7/22/09.

875—73.24(89A) Dumbwaiters. All dumbwaiters whether electric or hand powered shall conform to ANSI A17.1, 1971, section 700. Exceptions: Required rules for hoistway construction as set forth in ANSI A17.1, 1971, shall not apply to existing installations.

875—73.25(89A) Sprinkler retrofits and shunt trip breakers. Rescinded IAB 6/17/09, effective 7/22/09.

875—73.26(89A) Safety bulkheads. Rescinded IAB 6/17/09, effective 7/22/09.

875—73.27(89A) Child entrapment safeguards. This rule applies to a passenger elevator unless it has a car door consisting of a solid panel.

73.27(1) For purposes of this rule, "distance with deflection between the doors or gates" means the distance between the closed car door or gate and the closed hoistway door or gate measured at the greatest perpendicular distance with deflection.

73.27(2) For purposes of this rule, measurements of door or gate deflection shall be made in the manner described by ASME A17.1, section 2.14.4.6.

73.27(3) Door or gate deflection shall not exceed .75 inch.

73.27(4) If the distance with deflection between the doors or gates exceeds 5 inches, a means shall be provided to disable the elevator if a person is in the space between the closed doors or gates.

[**ARC 1972C**, IAB 4/29/15, effective 6/3/15; **ARC 2455C**, IAB 3/16/16, effective 4/20/16]

875—73.28(89) Elevators in broadcast towers. This rule applies to special purpose elevators located in broadcast towers.

73.28(1) *Anchorages.* Anchorages compliant with 29 CFR 1926.502(d)(15) shall be attached inside the car and on the car top.

73.28(2) *Emergency stop switch.* An emergency stop switch compliant with ASME A17.1, Sections 2.26.2.8 and 5.7.19, shall be installed on the car top.

[**ARC 2607C**, IAB 7/6/16, effective 8/10/16]

These rules are intended to implement Iowa Code chapter 89A.

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